EXAMINING PUBLIC HEALTH LEGISLATION TO HELP LOCAL COMMUNITIES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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C O N T E N T S

EXAMINING PUBLIC HEALTH LEGISLATION TO HELP LOCAL COMMUNITIES

WEDNESDAY, NOVEMBER 20, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 3:00 p.m., in room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Whitfield, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Pallone, Green, Barrow, Castor, and Waxman (ex officio).

Staff present: Noelle Clemente, Press Secretary; Brenda Destro, Professional Staff Member, Health; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Katie Novaria, Legislative Clerk; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and the Economy; Heidi Stirrup, Policy Coordinator, Health; Ziky Ababiya, Democratic Staff Assistant; Elizabeth Letter, Democratic Assistant Press Secretary; and Anne Morris Reid, Democratic Professional Staff Member.

Mr. PITTS. Thank you for your patience. I ask all guests please take their seats. The subcommittee will come to order. The Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today's legislative hearing examines seven important bipartisan public health bills aimed at improving the health of our families and communities. They are H.R. 1098, the Traumatic Brain Injury Reauthorization Act of 2013 introduced by Representative Bill Pascrell, which reauthorizes programs at the Centers for Disease Control and Prevention, CDC, to reduce the incidents of traumatic brain injury, TBI, and TBI surveillance systems and registries; H.R. 1281, the Newborn Screening Saves Lives Reauthorization Act of 2013 introduced by Representative Lucille Roybal-Allard, which reauthorizes Federal programs that provide assistance to States to improve and expand their newborn screening programs; H.R. 610, a bill to provide for the establishment of the Tick-Borne Diseases Advisory Committee introduced by Representative Chris Smith to ensure interagency coordination and communications on these diseases; H.R. 669, the Sudden Unexpected Death Data Enhancement

and Awareness Act, introduced by Ranking Member Pallone which provides for grants to help improve the understanding of sudden unexpected death; H.R. 2703, the Family Healthcare Accessibility Act of 2013 introduced by Representative Tim Murphy, which would provide Federal Tort Claims Act protection for health care professionals who volunteer their time at community health centers; H.R. 3527, the Poison Control Centers Reauthorization Act, a very well-crafted bill introduced by Representative Lee Terry and will reauthorize important activities related to poison control centers; and H.R. 3528, National All Schedules Prescription Electronic Reporting, NASPER, Reauthorization Act introduced by Representative Ed Whitfield, which will reauthorize the NASPER program to support State prescription drug monitoring programs.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's legislative hearing examines seven important, bipartisan public health bills aimed at improving the health of our families and communities. They are:

• H.R. 1098—the Traumatic Brain Injury Reauthorization Act of 2013, introduced by Rep. Bill Pascrell, which reauthorizes programs at the Centers for Disease Control and Prevention (CDC) to reduce the incidence of traumatic brain injury (TBI), and TBI surveillance systems and registries.

• H.R. 1281—the Newborn Screening Saves Lives Reauthorization Act of 2013, introduced by Rep. Lucille Roybal-Allard, which reauthorizes Federal programs that provide assistance to States to improve and expand their newborn screening programs.

• H.R. 610—a bill to provide for the establishment of the Tick-Borne Diseases Advisory Committee, introduced by Rep. Chris Smith to ensure interagency coordination and communication on these diseases.

• H.R. 669—the Sudden Unexpected Death Data Enhancement and Awareness Act, introduced by Ranking Member Pallone, which provides for grants to help improve the understanding of sudden unexpected death.

• H.R. 2703—the Family Health Care Accessibility Act of 2013, introduced by Rep. Tim Murphy, which would provide Federal Torts Claim Act protection for health care professionals who volunteer their time at community health centers.

• H.R. ——, the Poison Control Centers Reauthorization, will be introduced by Rep. Lee Terry, and will reauthorize important activities related to poison control centers.

• And H.R. ——, National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization Act, will be introduced by Rep. Ed Whitfield, will reauthorize the NASPER program to support State prescription drug monitoring programs.

I look forward to hearing from our witnesses, and I'd like to yield time to some of the sponsors of these bills.

[The information follows:]

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113TH CONGRESS
1ST SESSION

H. R. 1098

To amend the Public Health Service Act to reauthorize certain programs relating to traumatic brain injury and to trauma research.

IN THE HOUSE OF REPRESENTATIVES

MARCH 12, 2013

Mr. PASCRELL (for himself and Mr. ROONEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to reauthorize certain programs relating to traumatic brain injury and to trauma research.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Traumatic Brain Injury Reauthorization Act of 2013".

SEC. 2. CDC PROGRAMS FOR PREVENTION AND SURVEILLANCE OF TRAUMATIC BRAIN INJURY.

Section 394A of the Public Health Service Act (42 U.S.C. 280b–3) is amended—

(1) by striking the section heading and all that follows through "For the purpose" and inserting the following:

"SEC. 394. AUTHORIZATION OF APPROPRIATIONS.

"(a) IN GENERAL.—For the purpose"; and

(2) by adding at the end the following:

"(b) TRAUMATIC BRAIN INJURY.—To carry out sections 393B and 393C, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2014 through 2018.".

SEC. 3. STATE GRANTS FOR PROJECTS REGARDING TRAUMATIC BRAIN INJURY.

Section 1252 of the Public Health Service Act (42 U.S.C. 300d–52) is amended—

(1) in subsection (a), by striking ", acting through the Administrator of the Health Resources and Services Administration,"; and

(2) in subsection (j), by striking "2012" and inserting "2018".

SEC. 4. STATE GRANTS FOR PROTECTION AND ADVOCACY SERVICES.

Section 1253 of the Public Health Service Act (42 U.S.C. 300d–53) is amended—

(1) in subsection (a), by striking ", acting through the Administrator of the Health Resources

and Services Administration (referred to in this section as the 'Administrator'),";

(2) in subsections (c), (d)(1), (e)(1), (e)(4), (g), (h), and (j)(1), by striking "Administrator" each place it appears and inserting "Secretary";

(3) in subsection (i)—

(A) by striking "Administrator of the Health Resources and Services Administration" and inserting "Secretary"; and

(B) by striking "by the Administrator" and inserting "by the Secretary"; and

(4) in subsection (l), by striking "2012" and inserting "2018".

SEC. 5. INTERAGENCY PROGRAM FOR TRAUMA RESEARCH.

Section 1261(i) of the Public Health Service Act (42 U.S.C. 300d–61(i)) is amended by striking "2012" and inserting "2018".

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113TH CONGRESS
1ST SESSION

H. R. 1281

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2013

Ms. ROYBAL-ALLARD (for herself and Mr. SIMPSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Newborn Screening Saves Lives Reauthorization Act of 2013".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

Section 1109 of the Public Health Service Act (42 U.S.C. 300b–8) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "and in consultation with the Advisory Committee" and inserting "and taking into consideration the recommendations of the Advisory Committee";

(B) in paragraph (2), by striking "screening and training" and inserting "screening, counseling, and training"; and

(C) in paragraph (4), by striking "treatment" and inserting "followup and treatment";

(2) in subsection (b)—

(A) in paragraph (4), by striking "or" at the end;

(B) by redesignating paragraph (5) as paragraph (7); and

(C) by inserting after paragraph (4) the following:

"(5) a health professional organization;

"(6) an early childhood health system; or"; and

(3) by striking subsection (j) (relating to authorization of appropriations).

SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING AND FOLLOWUP PROGRAMS.

Section 1110 of the Public Health Service Act (42 U.S.C. 300b–9) is amended—

(1) in the section heading, by inserting "**AND FOLLOWUP**" after "**CHILD SCREENING**";

(2) in subsection (a), by inserting "followup," after "the effectiveness of screening,";

(3) in subsection (b)—

(A) in paragraph (1), by inserting "ascertainment, treatment," after "the effectiveness of screening, counseling,";

(B) in paragraph (2)—

(i) by inserting "ascertainment, treatment," after "the effectiveness of screening, counseling,"; and

(ii) by striking "or" at the end;

(C) in paragraph (3), by striking the period at the end and inserting "; or"; and

(D) by adding at the end the following:

"(4) the availability and effectiveness of treatment and followup care for newborns and their families after screening and diagnosis."; and

(4) by striking subsection (d) (relating to authorization of appropriations).

SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10) is amended—

(1) in subsection (b)—

(A) in paragraph (4), by striking "public health impact" and inserting "public health impact and cost"; and

(B) in paragraph (6)—

(i) in subparagraph (A), by striking "achieve rapid diagnosis" and inserting "achieve best practices in rapid diagnosis and appropriate treatment"; and

(ii) in subparagraph (D), by inserting before the semicolon ", including information on cost and incidence";

(2) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively;

(3) by inserting after subsection (e) the following new subsection:

"(f) MEETINGS.—The Advisory Committee shall meet in person at least twice each year.";

(4) by amending subsection (g), as redesignated by paragraph (2), to read as follows:

"(g) CONTINUATION OF OPERATION OF COMMITTEE.—

"(1) IN GENERAL.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate for the period beginning on the date of enactment of the Newborn Screening Saves Lives Reauthorization Act of 2013 and concluding at the end of the fifth fiscal year which begins after such date.

"(2) CONTINUATION IF NOT REAUTHORIZED.—If at the end of the fifth fiscal year described in paragraph (1) the duration of the Advisory Committee has not been extended by statute—

"(A) the Advisory Committee may be considered, for the purposes of the Federal Advisory Committee Act, to be an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act; and

"(B) the Secretary may renew the Advisory Committee under section 14(a)(1)(A) of such Act."; and

(5) by striking subsection (h) (relating to authorization of appropriations), as redesignated by paragraph (2).

SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

Section 1112 of the Public Health Service Act (42 U.S.C. 300b–11) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking "; and" and inserting a semicolon;

(B) in paragraph (3), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new paragraphs:

"(4) maintain current data on the number of conditions for which screening is conducted in each State; and

"(5) establish or disseminate guidelines for services and personnel necessary for followup, diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.";

(2) in subsection (b)(4)(D), by striking "Newborn Screening Saves Lives Act of 2008" and inserting "Newborn Screening Saves Lives Reauthorization Act of 2013"; and

(3) by striking subsection (d) (relating to authorization of appropriations).

SEC. 6. LABORATORY QUALITY.

Section 1113 of the Public Health Service Act (42 U.S.C. 300b–12) is amended—

(1) in subsection (a)—

(A) by striking the subsection enumerator and heading; and

(B) by striking "and in consultation with the Advisory Committee" and inserting "and taking into consideration the recommendations of the Advisory Committee"; and

(2) by striking subsection (b) (relating to authorization of appropriations).

SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

Section 1114 of the Public Health Service Act (42 U.S.C. 300b–13) is amended—

(1) in subsection (c), by striking "the Administrator, the Director of the Agency for Healthcare Research and Quality" and inserting "the Adminis-

trator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs,"; and

(2) by striking subsection (e) (relating to authorization of appropriations) and inserting the following:

"(e) REPORT TO CONGRESS.—

"(1) IN GENERAL.—The Secretary shall—

"(A) not later than 1 year after the date of enactment of the Newborn Screening Saves Lives Reauthorization Act of 2013, submit to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives a report on activities related to—

"(i) newborn screening; and

"(ii) screening children who have or are at risk for heritable disorders; and

"(B) not less than every 2 years, shall submit to such committees an updated version of such report.

"(2) CONTENTS.—The report submitted under subsection (a) shall contain a description of—

"(A) the implementation of sections 1111 through 1116B, including this section; and

"(B) the amounts expended on such implementation.".

SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

Section 1115(a) of the Public Health Service Act (42 U.S.C. 300b–14(a)) is amended by adding at the end the following: "The plan shall be updated as needed and at least every five years.".

SEC. 9. HUNTER KELLY RESEARCH PROGRAM.

Section 1116(a)(1) of the Public Health Service Act (42 U.S.C. 300b–15(a)(1)) is amended—

(1) in subparagraph (B), by striking "; and" and inserting a semicolon;

(2) by redesignating subparagraph (C) as subparagraph (E); and

(3) by inserting after subparagraph (B) the following:

"(C) providing research and data for newborn conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children to be added to the Recommended Uniform Screening Panel;

"(D) conducting pilot studies on conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and".

SEC. 10. NEWBORN SCREENING SURVEILLANCE, FOLLOWUP, AND APPLIED RESEARCH.

The Public Health Service Act is amended by inserting after section 1116 of such Act (42 U.S.C. 300b–15) the following:

"SEC. 1116A. NEWBORN SCREENING SURVEILLANCE, FOLLOWUP, AND APPLIED RESEARCH.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into cooperative agreements with, eligible entities to develop longitudinal followup and tracking programs for newborn screening.

"(b) PROGRAM.—Longitudinal followup and tracking programs developed through a grant under subsection (a) shall incorporate standardized procedures for data management and program effectiveness and costs, such as—

"(1) studying the costs and effectiveness of newborn screening, evaluation and intervention programs, and surveillance systems conducted by State-

based programs in order to answer issues of importance to State and national policymakers;

"(2) studying the effectiveness of newborn screening followup and intervention programs by assessing the health and development of children at school age and as young adults;

"(3) promoting the sharing of data regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs;

"(4) ensuring coordination of surveillance activities, including—

"(A) standardized data collection and reporting; and

"(B) use of electronic health records;

"(5) facilitating quality improvement in treatment and disease management based on gaps in services or care identified by longitudinal tracking systems; and

"(6) utilizing data from longitudinal tracking systems to support the development and evaluation of evidence-based guidelines for diagnosis, treatment, and disease management.

"(c) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means—

"(1) a State or a political subdivision of a State;

"(2) a consortium of 2 or more States or subdivisions described in paragraph (1);

"(3) a health facility or program operated by or pursuant to a contract with, or a grant from, the Indian Health Service; or

"(4) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.".

SEC. 11. AUTHORIZATION OF APPROPRIATIONS.

The Public Health Service Act is amended by inserting after section 1116A of such Act, as added by section 10 of this Act, the following:

"SEC. 1116B. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

"There are authorized to be appropriated—

"(1) to carry out sections 1109, 1110, 1111, and 1112, $13,334,000 for each of fiscal years 2014 through 2018;

"(2) to carry out section 1113, $7,500,000 for each of fiscal years 2014 through 2018; and

"(3) to carry out section 1116A, $5,000,000 for each of fiscal years 2014 through 2018.".

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113TH CONGRESS
1ST SESSION

H. R. 610

To provide for the establishment of the Tick-Borne Diseases Advisory Committee.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2013

Mr. SMITH of New Jersey (for himself, Mr. WOLF, Mr. GIBSON, and Mr. PETERSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To provide for the establishment of the Tick-Borne Diseases Advisory Committee.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this Act as the "Secretary") shall establish within the Office of the Secretary an advisory committee to be known as the Tick-

Borne Diseases Advisory Committee (referred to in this section as the "Committee").

(b) DUTIES.—The Committee shall advise the Secretary and the Assistant Secretary for Health regarding the manner in which such officials can—

(1) ensure interagency coordination and communication and minimize overlap regarding efforts to address tick-borne diseases;

(2) identify opportunities to coordinate efforts with other Federal agencies and private organizations addressing such diseases;

(3) ensure interagency coordination and communication with constituency groups;

(4) ensure that a broad spectrum of scientific viewpoints is represented in public health policy decisions and that information disseminated to the public and physicians is balanced; and

(5) advise relevant Federal agencies on priorities related to the Lyme and tick-borne diseases.

(c) MEMBERSHIP.—

(1) APPOINTED MEMBERS.—

(A) IN GENERAL.—The Secretary shall appoint the voting members of the Committee from among individuals who are not officers or employees of the Federal Government.

(B) GROUPS.—The voting members of the Committee shall include the following:

(i) At least 4 members from the scientific community representing the broad spectrum of viewpoints held within the scientific community related to Lyme and other tick-borne diseases.

(ii) At least 2 representatives of tick-borne disease voluntary organizations.

(iii) At least 2 health care providers, including at least 1 full-time practicing physician, with relevant experience providing care for individuals with a broad range of acute and chronic tick-borne diseases.

(iv) At least 2 patient representatives who are individuals who have been diagnosed with a tick-borne disease or who have had an immediate family member diagnosed with such a disease.

(v) At least 2 representatives of State and local health departments and national organizations that represent State and local health professionals.

(C) DIVERSITY.—In appointing members under this paragraph, the Secretary shall ensure that such members, as a group, represent a diversity of scientific perspectives relevant to the duties of the Committee.

(2) EX OFFICIO MEMBERS.—The Secretary shall designate, as nonvoting, ex officio members of the Committee, representatives overseeing tick-borne disease activities from each of the following Federal agencies:

(A) The Centers for Disease Control and Prevention.

(B) The National Institutes of Health.

(C) The Agency for Healthcare Research and Quality.

(D) The Food and Drug Administration.

(E) The Office of the Assistant Secretary for Health.

(F) Such additional Federal agencies as the Secretary determines to be appropriate.

(3) CO-CHAIRPERSONS.—The Secretary shall designate the Assistant Secretary for Health as the co-chairperson of the Committee. The appointed members of the Committee shall also elect a public

co-chairperson. The public co-chairperson shall serve a 2-year term.

(4) TERM OF APPOINTMENT.—The term of service for each member of the Committee appointed under paragraph (1) shall be 4 years.

(5) VACANCY.—A vacancy in the membership of the Committee shall be filled in the same manner as the original appointment. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Members may serve after the expiration of their terms until their successors have taken office.

(d) MEETINGS.—The Committee shall hold public meetings, except as otherwise determined by the Secretary, after providing notice to the public of such meetings, and shall meet at least twice a year with additional meetings subject to the call of the co-chairpersons. Agenda items with respect to such meetings may be added at the request of the members of the Committee, including the co-chairpersons. Meetings shall be conducted, and records of the proceedings shall be maintained, as required by applicable law and by regulations of the Secretary.

(e) REPORT.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter, the Committee, through the Director of the Centers for Dis-

ease Control and Prevention and the Director of the National Institutes of Health, shall submit a report to the Secretary. Each such report shall contain, at a minimum—

(1) a description of the Committee's functions;

(2) a list of the Committee's members and their affiliations; and

(3) a summary of the Committee's activities and recommendations during the previous year, including any significant issues regarding the functioning of the Committee.

(f) AUTHORIZATION OF APPROPRIATIONS.—Of the amounts made available to the Department of Health and Human Services for general departmental management for fiscal years 2013 through 2017, there is authorized to be appropriated $250,000 for each of such fiscal years to carry out this Act. Amounts made available to carry out this Act shall be used for the expenses and per diem costs incurred by the Committee under this section in accordance with the Federal Advisory Committee Act, except that no voting member of the Committee shall be a permanent salaried employee.

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113TH CONGRESS
1ST SESSION

H. R. 669

To amend the Public Health Service Act to improve the health of children and help better understand and enhance awareness about unexpected sudden death in early life.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2013

Mr. PALLONE (for himself and Mr. KING of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to improve the health of children and help better understand and enhance awareness about unexpected sudden death in early life.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Sudden Unexpected Death Data Enhancement and Awareness Act".

SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—SUDDEN UNEXPECTED INFANT DEATH AND SUDDEN UNEXPLAINED DEATH IN CHILDHOOD

"SEC. 399OO. DEFINITIONS.

"In this part:

"(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

"(2) DEATH SCENE INVESTIGATOR.—The term 'death scene investigator' means an individual certified as a death scene investigator by an accredited professional certification board.

"(3) DIRECTOR.—The term 'Director' means the Director of the Centers for Disease Control and Prevention.

"(4) STATE.—The term 'State' has the meaning given to such term in section 2, except that such term includes tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(5) SUDDEN UNEXPECTED INFANT DEATH; SUID.—The terms 'sudden unexpected infant death' and 'SUID' mean the sudden death of an infant under 1 year of age that when first discovered did not have an obvious cause. Such terms include those deaths that are later determined to be from explained as well as unexplained causes.

"(6) SUDDEN UNEXPLAINED DEATH IN CHILDHOOD; SUDC.—The terms 'sudden unexplained death in childhood' and 'SUDC' mean the sudden death of a child older than 1 year of age which remains unexplained after a thorough case investigation that includes a review of the clinical history and circumstances of death and performance of a complete autopsy with appropriate ancillary testing.

"SEC. 399OO–1. DEATH SCENE INVESTIGATION AND AUTOPSY.

"(a) INVESTIGATIONS.—

"(1) GRANTS.—The Secretary, acting through the Director, shall award grants to States to enable such States to improve the completion of comprehensive death scene investigations for sudden unexpected infant death and sudden unexplained death in childhood.

"(2) APPLICATION.—To be eligible to receive a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(3) USE OF FUNDS.—

"(A) IN GENERAL.—A State shall use amounts received under a grant under paragraph (1) to improve the completion of comprehensive death scene investigations for sudden unexpected infant death and sudden unexplained death in childhood, including through the awarding of subgrants to local jurisdictions to be used to implement standard death scene investigation protocols for sudden unexpected infant death and sudden unexplained death in childhood and conduct comprehensive, standardized autopsies.

"(B) PROTOCOLS.—A standard death scene protocol implemented under subparagraph (A) shall include the obtaining of information on current and past medical history of the infant/child, the circumstances surrounding the death including any suspicious circumstances, the sleep position and sleep environment of the

infant/child, and whether there were any accidental or environmental factors associated with the death. The Director in consultation with medical examiners, coroners, death scene investigators, law enforcement, emergency medical technicians and paramedics, public health agencies, and other individuals or groups determined necessary by the Director shall develop a standard death scene protocol for children from 1 to 4 years of age, using existing protocols developed for SUID.

"(b) AUTOPSIES.—

"(1) IN GENERAL.—The Secretary, acting through the Director, shall award grants to States to enable such States to increase the rate at which comprehensive, standardized autopsies are performed for sudden unexpected infant death and sudden unexplained death in childhood.

"(2) APPLICATION.—To be eligible to receive a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(3) COMPREHENSIVE AUTOPSY.—For purposes of this subsection, a comprehensive autopsy shall in-

clude a full external and internal examination, including microscopic examination, of all major organs and tissues including the brain, complete radiographs, vitreous fluid analysis, photo documentation, selected microbiology when indicated, metabolic testing, and toxicology screening of the infant or child involved.

"(4) GUIDELINES.—The Director, in consultation with board certified forensic pathologists, medical examiners, coroners, pediatric pathologists, pediatric cardiologists, pediatric neuropathologists and geneticists, and other individuals and groups determined necessary by the Director shall develop national guidelines for a standard autopsy protocol for sudden unexpected infant death and sudden unexplained death in childhood. The Director shall ensure that the majority of such consultation is with board certified forensic pathologists, medical examiners, and coroners. The Director is encouraged to seek additional input from child abuse experts, bereavement specialists, parents, and public health agencies on nonmedical aspects of the autopsy guidelines. In developing such protocol, the Director shall consider autopsy protocols used by State and local jurisdictions.

"(c) STUDY ON GENETIC TESTING.—The Director, in consultation with medical examiners, coroners, forensic pathologists, geneticists, researchers, public health officials, and other individuals and groups determined necessary by the Director, shall commission a study to determine the benefits and appropriateness of genetic testing for infant and early childhood deaths that remain unexplained after a complete death scene investigation and comprehensive, standardized autopsy. Such study shall include recommendations on developing a standard protocol for use in determining when to utilize genetic testing and standard protocols for the collection and storage of specimens suitable for genetic testing.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $8,000,000 for each of fiscal years 2014 through 2018 to carry out this section.

"SEC. 399OO–2. TRAINING.

"(a) GRANTS.—The Secretary, acting through the Director, shall award grants to eligible entities for the provision of training on death scene investigation specific for SUID and SUDC.

"(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall—

"(1) be—

"(A) a State or local government entity; or

"(B) a nonprofit private entity; and

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) USE OF FUNDS.—An eligible entity shall use amounts received under a grant under this section to—

"(1) provide training to medical examiners, coroners, death scene investigators, law enforcement personnel, and emergency medical technicians or paramedics concerning death scene investigations for SUID and SUDC, including the use of standard death scene investigation protocols that include information on the current and past medical history of the infant/child, the circumstances surrounding the death including any suspicious circumstances, the sleep position and sleep environment of the infant/child, and whether there were any accidental or environmental factors associated with the death;

"(2) provide training directly to individuals who are responsible for conducting and reviewing death scene investigations for sudden unexpected infant death and sudden unexplained death in childhood;

"(3) provide training to multidisciplinary teams, including teams that have a medical examiner or coroner, death scene investigator, law enforcement

representative, and an emergency medical technician or paramedic;

"(4) in the case of national and State-based grantees that are comprised of medical examiners, coroners, death scene investigators, law enforcement personnel, or emergency medical technicians and paramedics, integrate training under the grant on death scene investigation of SUID and SUDC into professional accreditation and training programs;

"(5) in the case of State and local government entity grantees, obtain equipment, including computer equipment, to aid in the completion of standard death scene investigation; or

"(6) conduct training activities for medical examiners, coroners, and forensic pathologists concerning standard autopsy protocols for sudden unexpected infant death and sudden unexplained death in childhood and integrate the training under the grant on standard autopsy protocols in SUID and SUDC into professional accreditation and training programs.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $2,000,000 for each of fiscal years 2014 through 2018.

"SEC. 399OO–3. CHILD DEATH REVIEW.

"(a) PREVENTION.—

"(1) CORE CAPACITY GRANTS.—The Secretary, acting through the Administrator, shall award grants to States to build and strengthen State capacity and implement State and local child death review programs and prevention strategies.

"(2) PLANNING GRANTS.—The Secretary, acting through the Administrator, shall award planning grants to States that have no existing child death review program or States in which the only child death review programs are State-based, for the development of local child death review programs and prevention strategies.

"(3) APPLICATION.—To be eligible to receive a grant under paragraph (1) or (2), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(4) TECHNICAL ASSISTANCE.—The Secretary, acting through the Administrator, shall provide technical assistance to assist States—

"(A) in developing the capacity for comprehensive child death review programs, including the development of best practices for the implementation of such programs; and

"(B) in maintaining the national child death case reporting system.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $7,000,000 for each of fiscal years 2014 through 2018 to carry out subsection (a).

"SEC. 399OO–4. ENHANCING THE NATIONAL CHILD DEATH CASE REPORTING SYSTEM.

"(a) IN GENERAL.—The Secretary, acting through the Director and in consultation with the national child death case reporting system, national health organizations, and professional societies with experience and expertise relating to reducing SUID and SUDC, shall modify such national death case reporting system, in accordance with subsection (b), to assure that such system provides for population-based data for ages 0 through 4 years of age and facilitates the understanding of the root causes, rates, and trends of SUID and SUDC with respect to such ages.

"(b) GOALS OF MODIFIED NATIONAL CHILD DEATH CASE REPORTING SYSTEM.—The modifications under subsection (a) to the national child death case reporting system shall facilitate the collection, analysis, and dissemination of data by—

"(1) implementing a surveillance and monitoring system based on thorough and complete death scene investigation data, clinical history, and autopsy findings;

"(2) collecting standardized information about the environmental, medical, genetic, and social circumstances of death (including sleep environment and quality of the death scene investigation) if determined that such may correlate with infant and early childhood deaths, as well as information from other law enforcement, medical examiner, coroner, emergency medical services (EMS), medical records, and vital records (if possible);

"(3) supporting multidisciplinary infant and early childhood death reviews such as those performed by child death review committees to collect and review the standardized information and accurately and consistently classify and characterize SUID and SUDC;

"(4) facilitating the sharing of information to improve the public reporting of surveillance and vital statistics describing the epidemiology of SUID and SUDC; and

"(5) utilizing current infrastructure of existing surveillance systems.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2014 through 2018.

"SEC. 399OO–5. PUBLIC AWARENESS AND EDUCATION CAMPAIGN.

"(a) ESTABLISHMENT.—The Secretary, acting through the Administrator and in consultation with the Director and the Director of the National Institutes of Health, shall establish and implement a culturally competent research-based public health awareness and education campaign to provide information that is focused on decreasing the risk factors that contribute to sudden unexpected infant death and sudden unexplained death in childhood, including educating individuals and organizations about safe sleep environments, sleep positions, and reducing exposure to smoking during pregnancy and after birth.

"(b) TARGETED POPULATIONS.—The campaign under subsection (a) shall be designed to reduce health disparities through the targeting of populations with high rates of sudden unexpected infant death and sudden unexplained death in childhood.

"(c) CONSULTATION.—In establishing and implementing the campaign under subsection (a), the Secretary shall consult with national organizations representing

health care providers, including nurses and physicians, parents, child care providers, children's advocacy and safety organizations, maternal and child health programs and women's, infants', and children's nutrition professionals, and other individuals and groups determined necessary by the Secretary for such establishment and implementation.

"(d) GRANTS.—

"(1) IN GENERAL.—In carrying out the campaign under subsection (a), the Secretary shall award grants to national organizations, State and local health departments, and community-based organizations for the conduct of education and outreach programs for health care providers, parents, child care providers, public health agencies, and community organizations.

"(2) APPLICATION.—To be eligible to receive a grant under paragraph (1), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $7,000,000 for fiscal year 2014 and $5,000,000 for each of fiscal years 2015 through 2018.

"SEC. 399OO–6. GRANTS FOR SUPPORT SERVICES.

"(a) IN GENERAL.—The Secretary, acting through the Administrator, shall award grants to national organizations, State and local health departments, and community-based organizations, for the provisions of support services to families who have had a child die of sudden unexpected infant death and sudden unexplained death in childhood.

"(b) APPLICATION.—To be eligible to receive a grant under subsection (a), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) USE OF FUNDS.—Amounts received under a grant awarded under subsection (a) may be used to provide grief counseling, education, home visits, 24-hour hotlines, and support groups for families who have lost a child to sudden unexpected infant death or sudden unexplained death in childhood.

"(d) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give preference to community-based applicants that have a proven history of effective direct support services and interventions for sudden unexpected infant death and sudden unexplained death in childhood and can demonstrate experience through collaborations and partnerships for delivering services throughout a State or region.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $500,000 for each of fiscal years 2014 through 2018.

"SEC. 399OO–7. EVALUATION OF STATE AND REGIONAL NEEDS.

"(a) IN GENERAL.—The Secretary, acting through the Director and in consultation with the Administrator, shall conduct a needs assessment on a State and regional basis of the availability of personnel, training, technical assistance, and resources for investigating and determining sudden unexpected infant death and sudden unexplained death in childhood and make recommendations to increase collaboration on a State and regional level for investigation and determination.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $250,000 for each of fiscal years 2014 through 2018.".

SEC. 3. ENHANCING PUBLIC HEALTH ACTIVITIES RELATED TO STILLBIRTH.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6. ENHANCING PUBLIC HEALTH ACTIVITIES RELATED TO STILLBIRTH.

"(a) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to eligible States and metropolitan areas to enhance and expand surveillance efforts to collect thorough and complete epidemiologic information on stillbirths, including through the utilization of the infrastructure of existing surveillance systems (including vital statistics systems).

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

"(1) be a State or a major metropolitan area (as defined by the Secretary); and

"(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(A) an assurance that the applicant will implement the standardized surveillance protocol developed under subsection (c); and

"(B) a description of the infrastructure of existing surveillance systems in the State or major metropolitan area, as applicable.

"(c) SURVEILLANCE PROTOCOL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(1) provide for the continued development and dissemination of a standard protocol for stillbirth data collection and surveillance, in consultation with representatives of health and advocacy organizations, State and local governments, and other interested entities determined appropriate by the Secretary;

"(2) monitor trends and identify potential risk factors for further study using existing sources of surveillance data and expanded sources of data from targeted surveillance efforts, and methods for the evaluation of stillbirth prevention efforts; and

"(3) develop and evaluate methods to link existing data to provide more complete information for research into the causes and conditions associated with stillbirth.

"(d) POSTMORTEM EVALUATION AND DATA COLLECTION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with physicians, nurses, pathologists, geneticists, parents, and other groups determined necessary by the Director, shall develop guidelines for increasing the performance and data collection of postmortem stillbirth evaluation, including conducting and reimbursing autopsies, placental histopathology, and cytogenetic testing. The guide-

lines should take into account cultural competency issues related to postmortem stillbirth evaluation.

"(e) PUBLIC HEALTH PROGRAMMATIC ACTIVITIES RELATED TO STILLBIRTH.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(1) develop behavioral surveys for women experiencing stillbirth, using existing State-based infrastructure for pregnancy-related information gathering; and

"(2) increase the technical assistance provided to States, Indian tribes, territories, and local communities to enhance capacity for improved investigation of medical and social factors surrounding stillbirth events.

"(f) PUBLIC EDUCATION AND PREVENTION PROGRAMS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with health care providers, public health organizations, maternal and child health programs, parents, and other groups deemed necessary by the Director, shall directly or through grants, cooperative agreements, or contracts to eligible entities, develop and conduct evidence-based public education and prevention programs aimed at reducing the occurrence of stillbirth overall and addressing

the racial and ethnic disparities in its occurrence, including—

"(1) public education programs, services, and demonstrations which are designed to increase general awareness of stillbirths; and

"(2) the development of tools for the education of health professionals and women concerning the known risk factors for stillbirth, promotion of fetal movement awareness, and the importance of early and regular prenatal care to monitor the health and development of the fetus up to and during delivery.

"(g) TASK FORCE.—The Secretary, in consultation with the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and health care providers, researchers, parents, and other groups deemed necessary by the Directors, shall establish a task force to develop a national research plan to determine the causes of, and how to prevent, stillbirth.

"(h) GRANTS FOR SUPPORT SERVICES.—

"(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants to national organizations, State and local health departments, and community-based organizations, for

the provisions of support services to families who have experienced stillbirth.

"(2) APPLICATION.—To be eligible to receive a grant under subsection (a), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(3) USE OF FUNDS.—Amounts received under a grant awarded under subsection (a) may be used to provide grief counseling, education, home visits, 24-hour hotlines, and support groups for families who have experienced stillbirth.

"(4) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give preference to applicants that are community-based organizations that have a proven history of providing effective direct support services and interventions related to stillbirths and can demonstrate experience through collaborations and partnerships for delivering services throughout a State or region.

"(i) DEFINITIONS.—In this section:

"(1) The term 'State' has the meaning given to such term in section 2, except that such term includes tribes and tribal organizations (as such terms

are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

"(2) The term 'stillbirth' means a spontaneous, not induced, pregnancy loss 20 weeks or later after gestation, or if the age of the fetus is not known, then a fetus weighing 350 grams or more.

"(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $3,000,000 for each of fiscal years 2014 through 2018.".

SEC. 4. REPORT TO CONGRESS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health and the Administrator of the Health Resources and Services Administration, shall submit to Congress a report describing the progress made in implementing this Act (and the amendments made by this Act).

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113TH CONGRESS
1ST SESSION

H. R. 2703

To amend the Public Health Service Act to provide liability protections for volunteer practitioners at health centers under section 330 of such Act.

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2013

Mr. MURPHY of Pennsylvania (for himself, Mr. GENE GREEN of Texas, Mr. DENT, Mr. DIAZ-BALART, Ms. MATSUI, Mr. BURGESS, Mr. SHUSTER, Mr. SARBANES, Mr. FORTENBERRY, Mrs. CAPITO, Mr. JOHNSON of Ohio, Mr. VELA, Ms. HANABUSA, and Mr. SCHOCK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to provide liability protections for volunteer practitioners at health centers under section 330 of such Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Family Health Care Accessibility Act of 2013".

SEC. 2. LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

"(q)(1) For purposes of this section, a health professional volunteer at an entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

"(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

"(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

"(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

"(C) The health care practitioner does not receive any compensation for the service from the individual or from any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

"(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

"(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

"(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or con-

tractor of an entity described in subsection (g)(4), subject to paragraph (4) and subject to the following:

"(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

"(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

"(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

"(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

"(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services per-

formed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

"(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

"(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

"(B) Not later May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding health professional volunteers to the same extent and in the same

manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

"(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

"(5)(A) This subsection takes effect on October 1, 2014, except as provided in subparagraph (B).

"(B) Effective on the date of the enactment of this subsection—

"(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

"(ii) reports under paragraph (4)(B) may be submitted to the Congress.".

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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to reauthorize the poison center national toll-free number, national media campaign, and grant program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. TERRY introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to reauthorize the poison center national toll-free number, national media campaign, and grant program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Poison Center Network Act".

SEC. 2. REAUTHORIZATION OF POISON CONTROL CENTERS NATIONAL TOLL-FREE NUMBER.

Section 1271 of the Public Health Service Act (42 U.S.C. 300d-71) is amended by striking subsection (b) and inserting the following:

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $700,000 for each of fiscal years 2015 through 2019 for the maintenance of the nationwide toll free phone number under subsection (a).".

SEC. 3. REAUTHORIZATION OF NATIONWIDE MEDIA CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION.

Section 1272 of the Public Health Service Act (42 U.S.C. 300d-72) is amended by striking subsection (d) and inserting the following:

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $800,000 for each of fiscal years 2015 through 2019.".

SEC. 4. REAUTHORIZATION OF THE POISON CONTROL CENTER GRANT PROGRAM.

(a) IN GENERAL.—Section 1273 of the Public Health Service Act (42 U.S.C. 300d-73) is amended—

(1) in subsection (a)—

(A) by striking "certified" and inserting "accredited"; and

(B) by striking "certification" and inserting "accreditation";

(2) in subsection (b)—

(A) in paragraph (1), by striking "establish" and inserting "research, establish, implement";

(B) by redesignating paragraphs (4) through (7) as paragraphs (5) through (8);

(C) by inserting after paragraph (3), the following:

"(4) to research, improve, and enhance the communications and response capability and capacity of the nation's network of poison control centers to facilitate increased access to the Centers through the integration and modernization of the current poison control centers communications and data system, including enhancing the network's telephony, Internet, data and social networking technologies;";

(D) in paragraph (6) (as so redesignated), by striking "paragraph (4)" and inserting "paragraph (5)"; and

(E) in paragraph (8) (as so redesignated), by striking "and respond" and inserting "and Internet communications, and to sustain and

enhance the poison control center's network capability to respond";

(3) in subsection (c)—

(A) in the subsection heading, by striking "CERTIFICATION" and inserting "ACCREDITATION";

(B) by striking "certified" each place that such term appears and inserting "accredited"; and

(C) by striking "certification" each place that such term appears and inserting "accreditation";

(4) in subsection (d)—

(A) in the subsection heading, by striking "CERTIFICATION" and inserting "ACCREDITATION";

(B) in paragraph (1)—

(i) by striking "the certification" and inserting "the accreditation";

(ii) by striking "a noncertified" and inserting "a nonaccredited"; and

(iii) by striking "a certification" and inserting "an accreditation"; and

(C) in paragraph (3)—

(i) by striking the last sentence; and

(ii) by striking "exceed 5 years." and inserting the following "exceed—

"(A) 5 years; or

"(B) in the case of a noncertified poison control center operating pursuant to a waiver under this subsection as of October 1, 2014, 6 years.";

(5) in subsection (f), by striking "for activities of the center" and inserting "for its activities"; and

(6) by striking subsection (g) and inserting the following:

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $28,600,000 for each of fiscal years 2015 through 2019. The Secretary may utilize an amount not to exceed 6 percent of the amount appropriated under this preceding sentence in each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions, which are determined by the Secretary to be appropriate for carrying out the program under this section.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to grants made on or after October 1, 2014.

[112H866]

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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

IN THE HOUSE OF REPRESENTATIVES

Mr. WHITFIELD introduced the following bill; which was referred to the Committee on _____

A BILL

To amend and reauthorize the controlled substance monitoring program under section 399O of the Public Health Service Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013".

SEC. 2. AMENDMENT TO PURPOSE.

Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

"(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

"(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

"(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and".

SEC. 3. AMENDMENTS TO CONTROLLED SUBSTANCE MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking "or";

(B) in subparagraph (B), by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(C) to maintain and operate an existing State-controlled substance monitoring program.";

(2) by amending subsection (b) to read as follows:

"(b) MINIMUM REQUIREMENTS.—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).";

(3) in subsection (c)—

(A) in paragraph (1)(B)—

(i) in the matter preceding clause (i), by striking "(a)(1)(B)" and inserting "(a)(1)(B) or (a)(1)(C)";

(ii) in clause (i), by striking "program to be improved" and inserting "program to be improved or maintained"; and

(iii) in clause (iv), by striking "public health" and inserting "public health or public safety";

(B) in paragraph (3)—

(i) by striking "If a State that submits" and inserting the following:

"(A) IN GENERAL.—If a State that submits";

(ii) by inserting before the period at the end "and include timelines for full implementation of such interoperability"; and

(iii) by adding at the end the following:

"(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).";

(C) in paragraph (5)—

(i) by striking "implement or improve" and inserting "establish, improve, or maintain"; and

(ii) by adding at the end the following: "The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in

accordance with the formula described in subsection (a)(2)(B).";

(4) in the matter preceding paragraph (1) in subsection (d), by striking "In implementing or improving" and all that follows through "(a)(1)(B)" and inserting "In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)";

(5) in subsections (e), (f)(1), and (g), by striking "implementing or improving" each place it appears and inserting "establishing, improving, or maintaining";

(6) in subsection (f)—

(A) in paragraph (1)(B) by striking "misuse of a schedule II, III, or IV substance" and inserting "misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act"; and

(B) by adding at the end the following:

"(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data and other information determined by

the Secretary to be necessary to enable the Secretary—

"(A) to evaluate the success of the State's program in achieving its purposes; or

"(B) to prepare and submit the report to Congress required by subsection (k)(2).

"(4) RESEARCH BY OTHER ENTITIES.—A department, program, or administration receiving non-identifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.";

(7) by redesignating subsections (h) through (n) as subsections (i) through (o), respectively;

(8) in subsections (e)(1)(A)(iv) and (d)(4), by striking "subsection (h)" each place it appears and inserting "subsection (i)";

(9) by inserting after subsection (g) the following:

"(h) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

"(1) facilitate prescriber use of the State's controlled substance monitoring system; and

"(2) educate prescribers on the benefits of the system both to them and society.";

(10) by amending subsection (l), as redesignated, to read as follows:

"(l) PREFERENCE.—Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant under title V that is related to drug abuse (as determined by the Secretary) and for which only States or tribes are eligible to apply, may give preference to eligible States with applications approved under this section, to eligible States or tribes with existing controlled substance monitoring programs that meet minimum requirements under this section, or to eligible States or tribes that put forth a good faith effort to meet those requirements (as determined by the Secretary).";

(11) in subsection (m)(1), as redesignated, by striking "establishment, implementation, or improvement" and inserting "establishment, improvement, or maintenance";

(12) in subsection (n)(8), as redesignated, by striking "and the District of Columbia" and inserting ", the District of Columbia, and any commonwealth or territory of the United States"; and

(13) by amending subsection (o), as redesignated, to read as follows:

"(o) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $7,000,000 for each of fiscal years 2014 through 2018.".

Mr. PITTS. I look forward to hearing from all of our witnesses, and I would like to yield the balance of my time to Dr. Murphy from Pennsylvania.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman. Health centers are quality low cost medical homes for millions, but they are more than just doctor's offices. They are a place where a child sees a pediatrician and an adult gets a checkup from their internist, someone can see the dentist or receive mental health care or prenatal care. Together, medical professionals at health centers coordinate care and work as a team saving nearly $25 billion each year, money that would otherwise be spent on caring for sicker patients in emergency rooms. That is the good news. But the sad news is there is a serious shortage of providers, and no matter how great the center, families can experience long delays because of the shortage.

Health centers located in medically underserved urban or rural areas report a 27 percent shortage of dentists, a 26 percent shortage of OB/GYNs, a 13 percent shortage of family physicians, and there are also shortages of psychiatrists and psychologists. The centers simply do not have enough money to hire additional staff required to cover the growing patient needs, but there is an answer.

Part-time and semi-retired health professionals want to help out but are unable to volunteer because of Federal barriers. Oddly enough, at Federal free clinics, volunteer providers receive medical malpractice coverage by the Federal Torts Claim Act. On the other hand, doctors and professionals employed by health centers are covered by the Federal Torts Claim Act, but volunteers at health centers don't get that liability protection, which then costs the centers thousands of dollars, and in some cases, well over 100,000 per year for these extra doctors. Clinics cannot afford that extra expense.

The Government Accountability Office has found that medical liability insurance costs poses a significant barrier for providers who otherwise would be eager to volunteer at health centers. The Family Health Care Accessibility Act fixes this disparity and opens the door for volunteer providers at clinics all over the country.

I want thank Chairman Pitts and Chairman Upton for holding this hearing, and my partner, a friend of this legislation, Gene Green of Texas. I also want to thank Bob MtJoy of Cornerstone Care in Washington, Greene County, for being here today to testify about the potential for this legislation to help millions of families. We have a chance to do something to expand care to millions of Americans with this act without raising the bills for families or taxpayers. This is an example of real bipartisan reform that helps people get the health care they need, when they need it close to home at an affordable cost. Isn't that what we all want in health care? Thank you, and I yield back.

Mr. PITTS. The Chair thanks the gentleman. Now yields 5 minutes to the lady from Florida, Ms. Castor, filling in for Ranking Member Pallone.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Well, thank you very much, Mr. Chairman, for calling this hearing today examining public health legislation to help our local communities. We are grateful to the public health experts, who we will hear from today, and I would also like to commend many of my colleagues who have offered legislation to combat some of the most serious public health problems facing many of our families all across this country, particularly when it comes to health centers, when it comes to newborn screening, poison control, and the terrible problem I am going to talk about a little bit later of pill mills and how we monitor the prescription drug abuse. So, thank you again, and at this time I am happy to yield to Mr. Waxman. Otherwise, he could take a full 5 minutes if he would like.

Mr. WAXMAN. I am going to wait till my turn.

Ms. CASTOR. OK. Then I will yield back. Thank you.

Mr. PITTS. The Chair recognizes the gentleman from Illinois, Mr. Shimkus, for 5 minutes.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman. My job is really to stall for Mr. Whitfield to get here, but since—that is a joke, so. It is good to have you-all here. What I—we get a lot of health care providers come to talk with us on public policy all the time, and what I always ask them in the end when they leave is to help us on the budgetary debate because we can authorize all we want, but if we don't solve or major budgetary problem, the discretionary budget keeps shrinking, which means less appropriations for the authorized committee, so you-all could help. I am not asking you to lobby, but I do ask you to get a good understanding of our real budgetary problems here and help us in that discourse.

Mr. Chairman, there is also another bill that I am not trying to put pressure, but I just want you to put on your record. It is H.R. 1252. We have got 90 cosponsors. It is called, "The Access to Care in Rural Communities," and it is really about physical therapy being defined within the primary health service for the purpose of the Health Services Corporation, and if you would take a look at that, that is bipartisan, and as we are talking about other bills that can be very helpful, I think that would be helpful for rural America.

And with that, I would offer to the—Marsha Blackburn for as much time as she may consume.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. I thank the gentleman from Illinois for yielding, and I just want to welcome each of you and to commend you for the work that you do and the role that you play, not only in delivering health care services but in the education component that is so vitally important to so many health care consumers, especially young moms, those that have experienced traumatic injury. It is something that many times we do not put enough emphasis upon,

and I appreciate that many of you are dedicated to that as a part of your core mission. With that, I yield back to the gentleman.

Mr. SHIMKUS. The gentlelady yields, and I yield back to you, Mr. Pitts.

Mr. PITTS. Would you yield to Mr. Pallone, please?

Mr. SHIMKUS. I would be honored to yield to the ranking member of the subcommittee.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you. I am not going to take up time because I know that Ms. Castor spoke on behalf of the Democrats, but I just wanted to thank—well, I should say a very special welcome to Laura Crandall from New Jersey. She and I have worked together for many years on the bill, my bill that is before the subcommittee today, and I just want to say that your strength and determination is commendable, so thank you. Thank you, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Chairman Pitts, and thank you to our witnesses for being here today; a very special welcome to Laura Crandall from New Jersey. She and I have worked together for many years on my bill that is before the subcommittee today. Your strength and determination is commendable.

I am happy that the subcommittee is having this hearing and moving forward with several public health bills. It is an important function of this subcommittee to examine public health priorities and to move legislation to promote and protect the public health. I would like to say a few words about each of the seven bills before us today.

Firstly, I am particularly pleased that we will be examining a bill that I introduced, H.R. 669, the Sudden Unexpected Death Data Enhancement and Awareness Act. Stillbirth and sudden unexpected infant death affect tens of thousands of families every year, according to data from CDC, and sudden infant death syndrome is the leading cause of death for infants up to 12months old. However, we currently lack the comprehensive, high-quality data we need to help better understand this problem.

My bill seeks to enhance CDC's activities in this area and would expand and standardize surveillance and data collection for stillbirth and sudden unexpected infant death and develop protocols and training for medical examiners for investigating these tragic deaths. I would like to submit for the record endorsement letters from 24 organizations, including the CJ Foundation, the American Academy of Pediatrics, and First Candle.

I am proud to be a cosponsor of another bill we will examine today. H.R. 1098, the Traumatic Brain Injury Reauthorization Act of 2013, was authored by my friend and colleague from New Jersey, Mr. Pascrell. Traumatic brain injury (or "TBI") has been dubbed "the silent epidemic," with at least 1.7 million TBI's occurring every year in the United States, manycausing death or permanent disability. This bill would continue efforts to advance better surveillance, prevention, and treatment of this serious public health problem.

We will also cover today, the Newborn Screening Saves Lives Reauthorization Act of 2013, which would update the 2008 law that established national newborn screening guidelines by expanding and improving State screening programs, parent and provider education, and follow-up care. Newborn screening allows thousands of infants every year the chance to recognize and manage detectable conditions early on, and it improves their chances of a more positive health outcome and better quality of life.

We will also hear from our witnesses on H.R. 610, a bill that would establish a Tick-Borne Diseases Advisory Committee within the Office of the Secretary of Health and Human Services to prioritize and coordinate efforts to address tick-borne diseases like Lyme disease. CDC estimates there are 300,000 cased of Lyme disease every year, and it is my understanding thatLyme disease is a growing threat in the

United States, due to ecological changes and changes in land use over the past few decades that have increased the number and proximity to humans of wild animal Lyme hosts and the ticks that can spread it to humans.

The fifth bill we will look at today is H.R. 2703, the Family Health Care Accessibility Act of 2013, which would decrease barriers to healthcare professionals volunteering at community health centers (or "CHCs"). CHCs provide vital access to care, especially for those underserved and vulnerable populations who can benefit most from the comprehensive, quality primarycare services these centers provide. For the over 22 million patients currently served by CHCs, it is important that these centers are adequately staffed.

Another bill we will consider today would reauthorize the poison control center grant program. I understand that poison exposure is a leading cause of unintentional injury in the United States, and poison control centers help to reduce the number of deaths and the severity of illness caused by poisoning.

Finally, I am glad that we are considering the National All Schedules Prescription Electronic Reporting (or "NASPER") Reauthorization, which I coauthored with my colleague from Kentucky, Mr. Whitfield. This legislation helps States set up prescription drug monitoring programs in order to combat prescription drug abuse, which is a growing epidemic in the United States. It is critical that we continue support for this program through Federal funding.

Thank you to the many Members who have led these important efforts by introducing these bills. I look forward to hearing from our witnesses on these important public health issues. Thank you.

Mr. PITTS. The Chair——

Mr. SHIMKUS. I am reclaiming my time. Now I would like to recognize Mr. Whitfield from the great State of Kentucky for the remainder of the time.

Mr. PITTS. All right. Two minutes.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Thank you very much. I appreciate it so much. And Chairman Pitts, I want to thank you for holding this hearing on this important topic, including H.R. 3528, the NASPER reauthorization as part of the discussion today. I would like to thank our witnesses for being here, particularly Dr. Steven Stack, a fellow Kentuckian from Lexington who will be testifying about the importance of prescription drug monitoring programs.

As you know, NASPER was authorized some years ago, we have always had a battle like a lot of other programs in obtaining sufficient money to make NASPER be what it should be. There is a companion program over at the Department of Justice, prescription drug monitoring, but it is more focused on law enforcement. So, I want to thank the chairman very much for working with us on this reauthorization and look forward to the testimony of the witnesses today.

And Mr. Shimkus, thank you so much for yielding me the time.

Mr. SHIMKUS. And I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman. I now recognize the ranking member of the full committee, Mr. Waxman, 5 minutes for opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I appreciate you holding this hearing. These bipartisan bills strengthen Depart-

ment of Health and Human Services programs on addressing new public health challenges. It is critical that this committee continues its focus on public health issues since our actions in the public health arena have such a far-reaching effect on the Nation's health.

We have a number of bills. H.R. 610 deals with the Lyme and other tick-borne diseases. There is the Sudden Unexpected Death Data Enhancement and Awareness Act. We have the H.R. 1098, Traumatic Brain Injury Reauthorization, and we have, also considering H.R. 1281, the Newborn Screening Saving Lives Reauthorization Act, the Family Health Care Accessibility Act of 2013 allowing community health centers to offer malpractice insurance coverage to their employees, contractors, and officers with the—under the Federal Tort Claim Act; H.R. 3527, the Poison Center Network Act, which reauthorizes the Poison Control Program; and then H.R. 3528, the National All Schedules Prescription Electronic Reporting Act—Reauthorization Act of 2013.

I have longer statements about each of these, which I will put into the record, but I want to commend a Democratic and Republican Energy and Commerce Committee members and their staffs who have authorized a number of the bills before us, Mr. Pallone, Mr. Engel, Green, Whitfield, Terry, and Murphy, and acknowledge the sponsors of the other measures, Congresswoman Roybal-Allard, Congressman Pascrell, Congressman Smith.

We have a panel of stakeholders to share their views on these bills, and I want to thank each of you for—in advance for your testimony. I don't want to be parochial, but Dr. McCabe was from California, but wherever you are from, we have a national perspective to protect the public health, and so I want to welcome all of you here today.

Mr. Chairman, I also hope we can work together on getting the administration's input on each of these measures as they move forward. With those comments, I will yield back the balance of my time.

[The prepared statement of Mr. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

Mr. Chairman, thank you for convening this afternoon's hearing on bipartisan bills that strengthen existing Department of Health and Human Services programs or address new public health challenges. It is critical that this committee continues its focus on public health issues, since our actions in the public health arena have such a far-reaching effect on the Nation's health.

H.R. 610 would establish a committee to advise the Secretary of HHS on the Department's Lyme and other tick-borne disease activities. The Centers for Disease Control and Prevention reports there has been a reemergence of tick-borne disease—with hundreds of thousands of estimated annual Lyme disease cases alone.

The Sudden Unexpected Death Data Enhancement and Awareness Act or H.R. 669 addresses three, devastating health events—stillbirth, the unexpected loss of an infant, and the unexpected death of a child.

Thousands of expectant mothers and parents experience a later-stage pregnancy loss or death of an infant due to causes that are not immediately apparent. Less is known about the unexplained deaths of young kids, like the daughter of one of today's witnesses—Ms. Crandall. H.R. 669 seeks to improve our understanding of the causes of these tragic events—and, in turn, help us to better prevent them.

H.R. 1098 or the Traumatic Brain Injury Reauthorization Act of 2013 extends TBI surveillance and research activities, and programs for services and supports administered across the Department. Millions of Americans experience a traumatic brain injury each year. One goal of H.R. 1098 is to allow the Department to better coordi-

nate TBI activities with other HHS programs focused on increased access to community supports.

We are also considering H.R. 1281, the Newborn Screening Saves Lives Reauthorization Act of 2013. This legislation extends newborn screening services and related activities forconditions like sickle cell anemia—that are not otherwise apparent at birth and, if left untreated, can cause severe disability or even death.

The Family Health Care Accessibility Act of 2013, H.R. 2073, would allow community health centers to offer malpractice coverage available to their employees, contractors, and officers under the Federal Tort Claims Act to health practitioner volunteers. In doing so, H.R. 2073 seeks to eliminate possible disincentives for health practitioners to volunteer. The House passed similar legislation during the 111th Congress.

H.R. 3527 or the Poison Center Network Act reauthorizes the Poison Control Program. Federal funding for the Nation's poison control centers supports the provision of treatment advice on poisonings to health professionals and the public; educational activities; and poison exposure surveillance efforts. The poison control network plays an important role in reducing the number of injuries and deaths resulting from poisoning and overdose

The final bill is H.R. 3528, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013, a second measure related to overdose. The NASPER Reauthorization Act would extend the Department's prescription drug monitoring program first authorized in 2005 and strengthen the interoperability of State NASPER programs.

During a June subcommittee hearing, witnesses described how programs like this one help respond to the prescription drug overdose epidemic. Congress also passed legislation nearly identical to H.R. 3528 during the 111th Congress. I want to commend the Democratic and Republican Energy and Commerce Members who authored a number of the bills before us—Ranking Member Pallone and Congressmen Engel, Green, Whitfield, Terry, and Murphy. I'd also like to acknowledge the sponsors of the other measures—Congresswoman Roybal-Allard, Congressman Pascrell, and Congressman Smith.

We have a panel of stakeholders to share their views on these bills, and I want to thank each of the witnesses in advance for their testimony. Mr. Chairman, I also hope that we can work together on getting the administration's input on each of these measures as they move forward.

Mr. PITTS. The Chair thanks the gentleman. We will work with you, and I would like to seek unanimous consent at this time to enter six documents into the record. First, a letter from the National Association of Boards of Pharmacy; second, statement from the National Association of Chain Drug Stores; thirdly, a letter from the National Organization for Injury and Violence Prevention; fourthly, letter from the Infectious Diseases Society of America; fifth, letter from National Association for States United for Aging and Disabilities; and sixth, a letter from the Alliance to Prevent Abuse of Medicines. Without objection, so ordered. They will be entered into the record.

[The information follows:]

National Association of Boards of Pharmacy

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November 20, 2013

Honorable Joe Pitts
Chairman, Subcommittee on Health
Committee on Energy and Commerce
US House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Frank Pallone, Jr
Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
US House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Chairman Pitts and Ranking Member Pallone:

The National Association of Boards of Pharmacy® (NABP®) regrets not being able to attend the November 20, 2013 United States House of Representatives, Committee on Energy and Commerce, Subcommittee on Health hearing entitled, "Examining Public Health Legislation to Help Local Communities," but is pleased to provide the following written comment as it pertains to the discussion draft to amend and reauthorize the National All-Schedules Prescription Electronic Reporting (NASPER) program. NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP Comments and Recommendations:
As written, the NASPER discussion draft allows NASPER funds to be used to maintain and operate a prescription monitoring program (PMP) rather than just establishing or improving a PMP. NABP fully supports this major change from previous legislation. Several states have come within weeks of shutting down and one state delayed implementing its PMP for many months until funds became available. Additionally, the Purpose section of the bill now acknowledges use of PMP data by law enforcement and state regulatory/licensing agencies.

Finally, NABP wishes to note that though the requirements of this draft apply only to states that receive a grant and not to those states that support their PMP via other mechanisms, states that do not receive grants may still be affected (eg, a state that receives grant is required to be interoperable with one or more border states whether the border state has a grant or not).

Comments on particularly important provisions follow:

1. (c)(1)(B)(iii) – This section requires interoperability with at least one state. This seems to conflict with Section (c)(3) which can be interpreted to require interoperability with all border states. See next item.

   (c)(3) Interoperability. As interpreted, if a state applies for a grant and has a border state(s) with a PMP, the state must be interoperable or have a plan and a timeline to achieve interoperability. This appears to necessitate every state (that applies for a grant) to be interoperable with every border state. There are statutory and political issues that will be problematic in some states. NABP believes that the language should allow an exemption of this requirement if achieving interoperability (with a particular state) is beyond the control of the state applying for the grant. However, if the state submitting the application cannot or will not share data with another PMP, that state should be disqualified from receiving funds.

2. (f)(1) – This section states, "*. . . a State may disclose information from the database . . .* ***only*** *in response to a request by—.*" Does this language limit the entities to whom a state may disclose information, if the state receives grant funds? If so, NABP suggests that the text be revised to read "*. . . a State may disclose information from the database . . .* ~~*only*~~ *in response to a request* ***only*** *by—.*"

   > Please note that a number of states allow access to several entities that are not described in this list (eg, Medicaid staff, workers' compensation staff, mental health workers, etc).

   Alternatively, if this section is interpreted to mean that disclosures are only provided pursuant to a request (as opposed to unsolicited), then this language could conflict with Section (f)(2)(A), which requires identification and notification to practitioners and dispensers of patients that may be involved in diversion or misuse of drugs. Thus, Section (f)(2)(A) seems to require unsolicited notification or disclosure of the identity of specific patients.

   NABP is advocating for clarity in both sections.

3. (f)(1)(B) – This provision seems to allow law enforcement access only to controlled substances in Schedules II, III, and IV. Many states maintain data for Schedule V substances and a few non-controlled drugs as well. Is this the intent or should the language be broadened to cover any substance for which the state maintains prescriptions records?

4. (f)(1)(D) – This section permits agents of specific agencies to obtain data for research. Section (g)(2) could be interpreted that these agencies listed in Section (f)(1)(D) receive only nonidentifiable data or that they may receive data with person identities but may further release only de-identified data. NABP is requesting clarity on the intent and recommends that only de-identified/nonidentifiable data be released to anyone for research.

5. (f)(3) – This section requires a state that receives a grant to provide aggregate data to the secretary. NABP recommends that this be clarified as "de-identified" or "nonidentifiable".

6. (f)(4) – Many universities and non-profit organizations seek de-identified data for legitimate research. This section seems to require that they obtain data from one of the organizations or agencies listed in Section (f)(1)(D). NABP recommends that the de-identified data be available

directly from the state PMP, subject to appropriate restrictions that limit the disclosure to legitimate scientific research.

7. Regarding Sections (k)(1) and (k)(2), which are part of the original NASPER language:

    a. Since substantial negative impacts in Section (k)(1) have not been documented since 2005 when the original NASPER language was passed, NABP recommends this section be deleted.

    b. Section (k)(2) requires a study of state PMPs' progress and the feasibility of certain new features. Much of this work is already documented and states are still making improvements in access and data quality each year. NABP does not believe there is a need to require one or more studies on these issues since studies are expensive and the progress is already occurring without federal oversight.

8. (l) – This section restates one of the original requirements but changes it from a "shall" to a "may." This change will give the secretary more flexibility in awarding competitive grants under Title V to states. NABP agrees with this change.

9. (n)(8) – This section defines the term "State." This should insure that the funds allocated are provided only to PMPs and not to other entities for purposes other than establishing, improving, or maintaining a state PMP. NABP agrees with this as defined.

NABP appreciates this opportunity to provide comments to the House Committee on Energy and Commerce, Subcommittee on Health. Please feel free to contact me with any questions at exec-office@nabp.net or via phone at 847/391-4400.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director Secretary

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

of:

The National Association
of Chain Drug Stores

for:

U.S. House of Representatives
Energy and Commerce Committee

Subcommittee on Health

Hearing on:

"Examining Public Health Legislation to
Help Local Communities"

November 20, 2013
2:00 p.m.
2123 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
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Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Subcommittee on Health for the opportunity to submit a statement for the hearing entitled "Examining Public Health Legislation to Help Local Communities." In particular, we would like to share our perspective on the National All-Schedules Prescription Electronic Reporting Act (NASPER). NACDS has endorsed legislation in the past to reauthorize NASPER because prescription drug monitoring programs (PDMPs) provide critical tools in efforts to curb and control prescription drug diversion and abuse.

As the face of neighborhood healthcare, community retail pharmacies are committed to ensuring that prescription medications are used appropriately and that local communities are safe. While most individuals take prescription medications responsibly, we recognize that the potential exists for controlled substances to be diverted and abused. Most states now utilize PDMPs as a tool to curb controlled substance abuse. Chain pharmacies work with state PDMPs in all states that have them. These programs warrant the federal support provided by NASPER.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic

impact of all retail stores with pharmacies transcends their over $1 trillion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.81 in other industries, for a total economic impact of $1.81 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

Background

We understand that a goal of NASPER is to provide grant money to states to encourage them to establish controlled substance prescription monitoring programs or to upgrade existing controlled substance prescription monitoring programs. NASPER also establishes standards that the state programs must follow in order to be eligible for the grant money.

NACDS and the chain pharmacy industry are committed to partnering with federal and state agencies, law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug abuse. Our members are engaged daily in activities with the goal of preventing drug abuse.

Recognizing the important role of PDMPs in helping to prevent drug abuse and diversion, chain pharmacies actively support PDMPs that are well designed to achieve program aims in a manner that does not disrupt the provision of patient care and the legitimate practices of pharmacy and medicine, and have minimal administrative burden associated with compliance.

These monitoring programs offer many benefits to aid in curbing prescription drug abuse. For example, they aid in identifying, deterring, and preventing drug diversion and abuse. These programs encourage appropriate intervention to determine if a person may have a drug addiction, so that treatment may be facilitated. The programs also provide public information on trends in drug abuse and diversion.

Chain pharmacy support is important to the success of PDMPs. Pharmacies submit information on the controlled substances they dispense. This includes information on the patient, prescribed drug dosage and quantity, and the prescriber. This information allows the state to conduct confidential reviews to determine any patterns of potential abuse or diversion.

Recommendations

PDMPs must be workable so that chain pharmacies are able to comply and submit the data that is needed for the successful operation of PDMPs. It is important that programs be appropriately designed so that they are not administratively burdensome or disruptive to providing patient care and the legitimate practices of pharmacy and medicine. When implementing or upgrading PDMPs, policymakers should consider the following factors to assure that PDMPs meet their goals.

- Provider Access to Prescription Monitoring Program Data

Many PDMPs grant healthcare providers access to information in the program databases on specific patients they are treating or considering treating. NACDS supports making

access to prescription monitoring program data available to healthcare providers, including pharmacists, for this purpose. However, states should not mandate use of the data by pharmacists. Ultimately, whether it is appropriate to run a report on a particular patient should left to the professional discretion of the pharmacist.

To increase the likelihood of healthcare providers using the program data, policymakers should work to ease the administrative burdens that providers experience when accessing data. Running reports in the prescription monitoring program can be a time-consuming process. Anecdotally, we have heard that it can take between 3-5 minutes to run a report on an individual patient from the online systems that most state programs have in place, which can be a deterrent to provider access for busy healthcare professionals. To address this, policymakers should allow healthcare providers, such as pharmacists, who have access to the database to identify delegates such as pharmacy technicians to access the program database to run reports on the providers' behalf, which would then be reviewed by the providers prior to prescribing or dispensing. Additionally, PDMPs should pursue program enhancements that can enable integration of prescription drug monitoring program into practitioner workflow. Improving accessibility of prescription monitoring program data ultimately eases administrative burdens that healthcare providers encounter when attempting to access the program and encourages greater use of this information.

- Data Format and Elements

PDMPs should ensure that the specific reporting requirements and various data elements that dispensers must report are consistent with what is typical in other states, and should

not require reporting of extraneous "situational" fields or any state-specific information. To improve interstate interoperability, we urge policymakers to harmonize and standardize PDMP data as much as possible.

- Compliance Date

Pharmacies must be given sufficient time prior to the program's compliance date to update their pharmacy computer systems to meet the program's requirements. Providing pharmacies with at least 90 days after the effective date of new laws, implementing regulations or any program changes should accomplish this. However, depending on the scope of pharmacy computer system modifications necessary to comply with the program requirements, additional time may be necessary. All of this should be considered when a PDMP is upgraded or modified.

Interstate Connectivity and the Next Generation of PDMPs

We understand that another goal of NASPER has been to foster interstate connectivity of PDMPs. NACDS supports the establishment of a national, aggregated controlled substance database, as opposed to a patchwork of state databases. We believe that PDMP data interoperability will only be successful if the state PDMPs reside on a technology infrastructure that can support high utilization with rapid (i.e. millisecond) response times. Concern exists with the current ability of existing state technology infrastructure systems to provide this support. Resources and efforts over the last ten years have made some progress, but more efforts are essential. Accordingly, continued resources should

be brought to bear to fix the identified system deficiencies and to create a much needed comprehensive, national database.

A viable, parallel approach to creating a national, uniform data monitoring system is the expansion and accelerated use of e-prescribing for controlled substances. E-prescribing holds great promise to generate a robust database of real-time information that could be used by DEA, state enforcement officers, pharmacies, insurers, wholesalers, and other partners to assist with the proactive identification of prescription drug abuse. E-prescribing may additionally mitigate prescription forgeries, provide a deterrent effect for prescribers, and may eventually be integrated with PDMP data to allow immediate insights at the point of prescribing.

Conclusion

NACDS thanks the Subcommittee for consideration of our comments on NASPER and the utilization of PDMPs to address the problem of drug abuse. We are committed to the health and welfare of our patients and the communities they call home. We believe that PDMPs are critical tools in combating prescription drug abuse and we encourage providing resources to ensure the viability of PDMPs. Accordingly, we support NASPER.

National Organizations for Injury and Violence Prevention

November 19, 2013

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
United States Congress
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy & Commerce
United States Congress
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

The undersigned national organizations involved in injury and violence prevention urge you to support H.R. 1098, the Traumatic Brain Injury Reauthorization Act of 2013, which would reauthorize funding for the Centers for Disease Control and Prevention (CDC) to conduct brain injury surveillance, prevention, public education and awareness; funding for research conducted by the National Institutes of Health; and to improve service delivery and access through state and state protection and advocacy grant programs.

TBI remains a leading cause of death and disability in both adults and youth and is one of the signature injuries of returning services members and veterans. CDC's research and TBI programs work to prevent TBI and help people better recognize, respond, and recover if a TBI occurs. Primary funding to address this growing population is provided through CDC's Injury Center which has designated TBI as one of the four focus areas along with motor vehicle-related injuries; violence against children and youth; and prescription painkiller overdoses. The Center determines incidence and prevalence of TBI-related disabilities, including military-related TBIs; methods for determining mild TBI; and conducts public education and prevention activities to reduce falls-related TBIs among the elderly, concussions relating to sports, and brain injury as the result of shaken baby syndrome.

Reauthorizing TBI legislation is critical to keep these and other targeted national and state efforts in place in order to reduce the undue burden of TBI-related disabilities on families, caretakers and society as a whole. We strongly support this important legislation, which has been critical for states and other entities to address this serious public health issue.

Sincerely,

American Association of Neurological Surgeons
American Psychological Association
American Physical Therapy Association
American Trauma Society
Brain Injury Association of America
Child Injury Prevention Alliance
Congress of Neurological Surgeons
Council of State and Territorial Epidemiologists

Page 2, Support for H.R. 1098:
National Injury and Violence Prevention Organizations
November 19, 2013

National Association of County and City Health Officials
National Association of State EMS Officials
National Association of State Head Injury Administrators
National Center on Domestic and Sexual Violence
National Council on Aging (NCOA)
Road Safety Director, FIA Foundation
Safe Kids
Safe States Alliance

cc: Rep. Joe Pitts
Rep. Frank Pallone
Rep. Bill Pascrell, Jr.
Rep. Tom Rooney

IDSA
Infectious Diseases Society of America

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Arlington, VA 22209
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November 19, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joe Pitts
Chairman
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Chairman Murphy, and Chairman Pitts:

On behalf of the Infectious Diseases Society of America (IDSA), which represents more than 10,000 physicians and scientists, I urge the House Energy and Commerce Committee to act on the September 18, 2013 letter from Representatives Waxman, DeGette, Pallone, and Dingell that requests a hearing on the growing threat of antimicrobial resistance. A well-coordinated federal response is essential to lessening the human and financial costs associated with this public health crisis. We believe that the committee has an important ongoing role to play in highlighting antimicrobial resistance as a priority issue, advancing an appropriate policy framework, and providing oversight of federal antimicrobial resistance activities.

Antimicrobial resistance poses a threat to every American. In the recent report *Antibiotic Resistance Threats in the United States, 2013*, the Centers for Disease Control and Prevention (CDC) categorized and made public the list of antibiotic resistant pathogens that pose the most significant threat to the public. The CDC statement of two million Americans suffering antibiotic resistant infections each year, resulting in 23,000 deaths, is likely a considerable underestimate. Current surveillance and data collection capabilities cannot yet capture the full disease burden. Regarding financial impacts, according to CDC, $20 billion in excess health care costs and more than 8 million additional hospital days are attributable to antibiotic resistant infections each year in the United States. The CDC report recommended four core actions to address this crisis: prevention, surveillance, appropriate use of antibiotics, and the development of new antibiotics and

diagnostics. However, at present there is insufficient federal coordination of these efforts, progress or accountability. The Interagency Task Force on Antimicrobial Resistance, established in 1999, meets infrequently, lacks centralized, high level leadership, and needs a workable mechanism for regular communication with non-government experts.

It is imperative that Congress help facilitate a comprehensive and coordinated federal response. In 2012, with the passage of the Food and Drug Administration Safety and Innovation Act, Congress incentivized the development of new antibiotics by extending the length of time they are initially free from competition. Congressional leaders in this area and other key stakeholders recognize that this was a first step and that more incentives are needed. However, the development of new antibiotics is only part of the solution. We must address the underlying problem of resistance or new drugs will quickly lose their utility, placing patients at risk and squandering federal investments.

Once again, I ask that the House Energy and Commerce Committee hold a hearing on antimicrobial resistance as soon as possible. Additionally, I invite you to use IDSA as a resource in your deliberations on this topic. The time to act is now, while we still have an opportunity to prevent a post-antibiotic era in which we are unable to successfully treat infections or carry out many other health care activities (e.g. transplants, chemotherapy, care of preterm infants and others) currently made safe and possible by effective antibiotics. Should you have any questions, please contact Jonathan Nurse, Director of Government Relations for the Infectious Diseases Society of America, at 703-299-0202 or jnurse@idsociety.org. Thank you for the committee's efforts on behalf of the health of the nation.

Sincerely,

Barbara E. Murray M.D.

Barbara E. Murray, MD, FIDSA
President, IDSA

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November 19, 2013

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
United States Congress
2125 Rayburn House Office Building
Washington DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy & Commerce
United States Congress
2322A Rayburn House Office Building
Washington DC 20515

Dear Chairman Upton and Ranking Member Waxman:

I write today on behalf of the National Association of States United for Aging and Disabilities (NASUAD), to encourage you to reauthorize the Traumatic Brain Injury (TBI) Act, as outlined in the Traumatic Brain Injury Reauthorization Act of 2013 (HR 1098).

NASUAD represents the 56 officially designated state and territorial agencies on aging and disabilities. Each of our members oversees the implementation of the Older Americans Act (OAA), and many also serve as the operating agency in their state for Medicaid waivers that serve older adults and individuals with disabilities. Together with our members, we work to design, improve, and sustain state systems delivering home and community based services and supports for people who are older or have a disability, and their caregivers.

Each year, approximately 1.7 million Americans are treated through emergency departments and in-hospital stays due to TBI, which is the leading cause of death and disability in children and young adults. Troublingly, the number of Americans sustaining TBI is increasing, both as the result of the wars in Iraq and Afghanistan, and due to fall-related injuries among the nation's rapidly growing senior population.

First signed into law in 1996, the TBI Act is the only federal law that addresses the unique issues facing, and complex service needs of, individuals with TBI and their families. The Act's timely reauthorization is necessary to ensure the continued success of these programs, on which an increasing number of Americans rely to remain healthy and in their communities.

On March 12, 2013, Reps. Bill Pascrell, Jr. (D-NJ) and Tom Rooney (R-FL) introduced HR 1098 to reauthorize the TBI Act through 2018. NASUAD is pleased to support this bipartisan legislation, which we believe will improve both access to and the delivery of services, in part by expanding the current system's capacity to assist individuals with TBI obtain the services and supports they need.

Further, NASUAD supports HR 1098's proposed interagency transfer of the Federal TBI State Grant Program and the Protection & Advocacy (P&A) TBI Program. Though the bill

leaves the placement of these programs within HHS to the discretion of the Secretary, NASUAD recommends they be realigned as part of the Administration for Community Living (ACL).

Created in 2012, ACL serves as the federal agency responsible for increasing access to community supports while focusing attention and resources on the unique needs of older Americans and people with disabilities. Shifting the administration of these TBI programs from the Health Resources and Services Administration (HRSA) to ACL would facilitate greater collaboration between these and other aging and disability programs involved in service delivery across the lifespan at the federal, state, and local levels.

Reauthorization is an opportunity to prioritize and strengthen the TBI Act. To this end, we urge you to advance HR 1098. Thank you for your leadership on these critical issues, and we look forward to further collaboration.

Sincerely,

Martha A. Roherty

Martha A. Roherty
Executive Director
NASUAD

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Alliance to **Prevent** the
Abuse of **Medicines**

November 20, 2013

The Honorable Ed Whitfield
U.S. House of Representatives
2184 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Whitfield:

On behalf of the Alliance to Prevent the Abuse of Medicines, we would like to take this opportunity to thank you sincerely for your leadership efforts to address our nation's prescription drug abuse epidemic.

H.R. 3528, The National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013 (NASPER) is a critical piece of legislation providing grants to states to enhance their prescription drug monitoring programs (PDMPs). We strongly support this legislation and urge its swift passage through Congress with bipartisan, bicameral support. In addition, we strongly support full funding of this vital legislation in FY 2014.

PDMPs, of all programs to address the abuse of prescription drugs, represent the cornerstone health care tool to solving this public health dilemma by allowing early identification of at-risk patients and timely intervention to prevent prescription drug abusers from succumbing to criminal activity and consequently, reliance on public systems such as Medicaid or state block grant programs. Moreover, adequately funded PDMPs are the solution to helping states fight this epidemic. Accordingly, states must be provided full funding, as outlined in the NASPER Reauthorization legislation, to establish or significantly improve implemented PDMPs in four key areas: 1) information needs to be as comprehensive as possible; 2) information needs to be as current as possible, with states moving to "real time", 3) data must be linked to electronic health records, and 4) data must be collected and evaluated to determine what is effective.

By way of background, the Alliance to Prevent the Abuse of Medicines is a non-profit partnership of key stakeholders in the prescription drug supply chain, including manufacturers, distributors, pharmacy benefit managers, pharmacies, and physicians, that have joined together to develop and offer policy solutions aimed at addressing the prescription drug abuse epidemic. The mission of the Alliance is to raise awareness of the issue of prescription drug abuse, partner with legislators to craft achievable solutions, and serve as a resource for policymakers. As the only coalition focused on this issue that includes representation across the domestic pharmaceutical supply chain, the Alliance brings a comprehensive perspective to addressing the prescription drug abuse epidemic.

We look forward to serving as a resource to you and to the House Energy and Commerce Committee as the NASPER legislation moves through the reauthorization process, and again, would like to express our strong support for this important step in addressing the public health epidemic of prescription drug abuse.

Sincerely,

Alliance to Prevent the Abuse of Medicines

cc: The Honorable Fred Upton
Chairman, House Energy and Commerce Committee

The Honorable Joe Pitts
Chairman, House Energy and Commerce Committee Subcommittee on Health

The Honorable Henry A. Waxman
Ranking Member, House Energy and Commerce Committee

The Honorable Frank Pallone, Jr.
Ranking Member, House Energy and Commerce Committee Subcommittee on Health

Mr. PITTS. On our panel today we have introduce them at this time. Dr. Marsha Ford, president of the American Association of Poison Control Centers; Dr. Steven Stack, immediate past chair, Board of Trustees, American Medical Association; Dr. Drew Nagele, Board of Directors, Brain Injury Association of America; Dr. Edward McCabe, senior vice president, Chief Medical Officer of the Office of Medicine and Health Promotion, March of Dimes Foundation; Ms. Patricia Smith, president of the Lyme Disease Association; Ms. Laura Crandall, cofounder of Sudden Unexplained Death in Childhood Program; and finally, Mr. Robert MtJoy, CEO of Cornerstone Care.

I thank each of you for coming. Your prepared testimonies, written testimony will be placed in the record. You will each have 5 minutes to summarize your testimony, and so at this time, the Chair recognizes Dr. Ford for 5 minutes for a summary of her opening statement.

STATEMENTS OF MARSHA FORD, PRESIDENT, AMERICAN ASSOCIATION OF POISON CONTROL CENTERS; STEVEN J. STACK, IMMEDIATE PAST CHAIR, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; DREW NAGELE, BOARD OF DIRECTORS, BRAIN INJURY ASSOCIATION OF AMERICA; EDWARD R.B. MCCABE, SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, MARCH OF DIMES FOUNDATION; PATRICIA V. SMITH, PRESIDENT, LYME DISEASE ASSOCIATION, INC.; LAURA CRANDALL, PROGRAM DIRECTOR, SUDDEN UNEXPLAINED DEATH IN CHILDHOOD PROGRAM; AND ROBERT MTJOY, CHIEF EXECUTIVE OFFICER, CORNERSTONE CARE, INC.

STATEMENT OF MARSHA FORD

Ms. FORD. Thank you. Chairman Pitts, Ranking Member Pallone, and members of the subcommittee, I appreciate the opportunity to testify today in support of the reauthorization of the National Poison Center Program entitled "America's Poison Center Network Act." I am Dr. Marsha Ford, director of the Carolina's Poison Center In Charlotte, North Carolina and president of the American Association of Poison Control Centers, otherwise known as the AAPCC. The AAPCC is comprised of 56 regional poison centers that serve 100 percent of the population of the United States providing 24/7 real-time case triage and management advice for diverse multitude of poisoning problems.

I am pleased to have join me today Kathy Jacobitz, who is director of the Nebraska Regional Poison Center in Omaha, Nebraska, and John Fiegel, the interim executive director of the AAPCC. And on behalf of all AAPCC member centers, I wish to express our appreciation to Mr. Terry and Mr. Engel and to the very talented health staff, including respectably, Nick Magallenes and Heidi Ross for their leadership in helping craft this bipartisan reauthorization legislation.

The National Poison Center network legislation was first passed in Congress in 2000 and has been reauthorized twice. It is a highly successful truly public-private Federal, State, local partnership. It reduces unnecessary hospital visits, hospitalizations, and health

care cost in our country by 1.8 billion annually, according to the 2012 Lewin Group cost-benefit study and as restated in HRSA's annual report to Congress earlier this year.

The Poison Center Program is currently authorized through Public Law 110–377, the Poison Center Support, Enhancement, and Awareness Act of 2008. This program is legislatively mandated to do three things: Supply funding to support operations of poison centers, establish and maintain a single national toll-free number, and implement a nationwide media campaign to educate the public and health care providers about poison prevention, poison center services, and the toll-free number. These three essential components comprise what is being requested for funding in this reauthorization bill.

What key services do poison centers provide? I will briefly describe four: First, we provide assistance in triaging, diagnosing, and managing victims of a multitude of toxic exposures and public health emergency situations. We do this for the public, for health care providers, for emergency response personnel, and others. We do this for all people, including underserved and vulnerable populations. We do this for all ages and all types of problems. We do this for physicians and other health care providers who increasingly utilize poison centers for toxicological expertise. Emergency 911 dispatchers refer poison-related calls to poison centers, often avoiding unnecessary EMS transports.

Altogether, in 2012, the Nation's poison centers handled nearly 3.4 million cases and made 2.7 million follow-up calls to ascertain the status of the caller or the patient. And we do this at no cost to the caller.

Poisoning is a major public health problem and is now the leading cause of injury death in the United States, having surpassed motor vehicular deaths. Poisonings are expensive. In 2009, an estimated 4.4 billion was spent on health care for poisoned patients. Poison centers are an antidote for some of the spending. In 2011, use of the Nation's poison centers avoided an estimated 1.7 million unnecessary health care visits and decreased hospital lengths of stay for some patients.

A second function of poison centers is the collection of poison exposure and disease surveillance data. Multiple Federal agencies use this data for surveillance to identify, characterize, and track public health threats. One example, early recognition of the toxicity of unit dose, laundry detergent packets in small children. In a great sense of timing, The Wall Street Journal had a front page article about this in yesterday's paper.

Poison centers also provide case triage and management advice in specific public health events. Something I am very excited about, the AAPCC and its member centers are working with the CDC to design a coordinated national network that will provide telemedicine services during a severe influenza pandemic to triage cases and selectively provide anti-virile medications, thus reducing medical surge on health care facilities and allowing more appropriate use of these medical resources.

Once created, this network may be capable of providing services during other public health emergencies.

A third function, poison centers provide poisoning prevention education to the public and clinical education to health care providers.

And finally, a fourth function, participation in emergency preparedness. The surveillance system that I mentioned earlier enables detection and monitoring of public health and environmental emergencies involving toxic exposures and pandemics. The value of poison centers has been demonstrated in national emergencies such as the Gulf Oil spill, the H1N1 outbreak, and the Fukushima Nuclear Accident. Medical toxicologists from poison centers assist the Department of Homeland Security with risk assessment of chemical threats.

Tens of millions of American families and tens of thousands of health care professionals have used poison centers services, experiencing firsthand the value of the Nation's poison center network.

Thank you again for this opportunity to highlight the value and importance of the National Poison Center Program. The Nation's poison centers, your poison centers strongly support the proposed Terry-Engel reauthorization legislation of the poison center program that is before the subcommittee today. Thank you.

Mr. PITTS. The Chair thanks the gentlelady.

[The prepared statement of Ms. Ford follows:]

STATEMENT BY:

DR. MARSHA FORD, MD, FACEP, FACMT,
Director of the Carolinas Poison Center,
Charlotte, North Carolina and
President of the American Association of Poison Control Centers

REGARDING THE REAUTHORIZATION OF THE NATION'S POISON CONTROL CENTER LAW

BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES HEARINGS ON "EXAMINING PUBLIC HEALTH LEGISLATION TO HELP LOCAL COMMUNITIES"

20 NOVEMBER 2013

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today in support of the reauthorization of the national poison center program entitled "America's Poison Center Network Act." I am Dr. Marsha Ford, Director of the Carolinas Poison Center in Charlotte, North Carolina and President of the American Association of Poison Control Centers ("AAPCC"). The AAPCC is comprised of 56 regional poison centers that serve 100% of the population of the United States, 24x7, with real-time poisoning, toxic exposure, food-borne illness and public health emergency case triage and management advice.

I am pleased to have join me today Kathy Jacobitz, Director of the Nebraska Regional Poison Center in Omaha, Nebraska, and John Fiegel, Interim Executive Director of the AAPCC. On behalf of all the AAPCC member centers and particularly Kathy and John, I wish to express our appreciation to Mr. Terry and Mr. Engel, and their very talented health staff, including Nick Magallenes and Heidi Ross, respectively, for their leadership in helping craft this bi-partisan reauthorization legislation.

The national poison center network legislation was first passed by Congress in 2000 and has been reauthorized twice since then. It is a highly successful, true public-private, federal-state-local partnership that reduces unnecessary hospital visits, hospitalizations and health care costs in our country by more than $1.8 billion annually according to the 2012 Lewin Group cost-benefit study and restated in HRSA's annual report to Congress earlier this year.

The Poison Center Program is currently authorized through Public Law 110-377, the Poison Center Support, Enhancement, and Awareness Act of 2008. The Poison Center Program is legislatively mandated to fund poison centers; establish and maintain a single, national toll-free number (800) 222-1222) to ensure universal access to poison center services and connect callers to the poison center servicing their area; and implement a nationwide media

campaign to educate the public and health care providers about poison prevention, poison center services and the 800 number.

Poison centers are a key primary defense in the United States against injury and deaths from poisoning. Twenty-four hours a day, the general public as well as health care practitioners and emergency response personnel contact their local poison centers for help in triaging, diagnosing and treating victims of poisonings, prescription drug misuse and a multitude of toxic exposures and public health emergency situations. In 2012, nearly 3.4 million cases (more than 9,200 per day) were managed by the nation's 56 poison centers; approximately half of these cases involved children under the age of six who were exposed to toxins in their home. Poison centers provide ready and direct access to vital emergency health information for all people of the United States, including underserved and vulnerable populations.

Poisoning has now become the leading cause of injury death in the United States. According to the United States Department of Health and Human Services, Centers for Disease Control and Prevention ("CDC"), December 2011 National Center for Health Statistics report over 40,000 people died as a result of poisoning in 2008. In 2009 poisonings accounted for 438,244 hospitalizations, 1,532,523 days of acute hospital care, and 2,144,188 emergency department and physician office visits, resulting in annual health care spending of more than $4.4 billion.[1]

In September 2012, the National Academy of Sciences Institute of Medicine, in its study "Best Care At Lower Cost," estimated that in 2009 America's health care system wasted $765 billion, or 31% of every dollar spent. Of this number, $265 billion was wasted on unneeded health care services and missed prevention opportunities. In contrast, America's utilization of

[1] Value of the Poison Center System: Lewin Group Report for the American Association of Poison Control Centers. 2011.

the nation's poison center information and case triage services resulted in avoiding more than 1.7 million unnecessary visits and decreasing hospital length of stay in United States health care facilities in 2011.

For over 50 years, the nation's poison centers have been a key primary defense against injury and death from poisonings. Twenty-four hours a day, seven days a week, care providers and other specially trained poison experts provide poisoning case triage and treatment recommendations at no cost to the caller. Poison centers are not only consulted when children get into household products, but also when seniors and people of all ages take too much medicine or when workers are exposed to harmful substances on the job. Emergency 911 dispatchers refer poison-related calls to poison centers, and health care professionals regularly consult poison centers for expert advice on unusual or complex cases. Poison centers are a critical resource for emergency preparedness and response as well as for other public health emergencies.

Multiple studies have demonstrated that accurate assessment and triage of poison exposures by poison centers save dollars by reducing severity of illness and death and eliminating or reducing unnecessary healthcare expenditures. Consultation with a poison center can also significantly decrease the patient's length of stay in a hospital and decrease hospital costs.[2,3,4,5] In fact, utilization of poison centers by health care facilities and physicians continues

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[2] Vassilev ZP, Marcus SM. Impact of a poison control center on the length of hospital stay for patients with Poisoning. J. Toxicol. Environ. Health Part A. 2007; 70(2): 107-110.

[3] Zaloshnja, E.; Miller, T.R.; Jones, P.; Litovitz, T.; Coben, J.; Steiner, C.; Sheppard, M. (2006). The potential impact of poison control centers on rural hospitalization rates for poisonings. Pediatrics. 118(5), 2094-2100.

[4] Healthcare Cost and Utilization Project [HCUP] (2007). 2005 National Inpatient Sample. Rockville, MD: Agency for Healthcare Research and Quality, Department of Health and Human Services.

[5] Zaloshnja, E.; Miller, T.R.; Jones, P.; Litovitz, T.; Coben, J.; Steiner, C.; Sheppard, M. The impact of poison control centers on poisoning-related visits to emergency departments, U.S. 2003. Am. J. Emerg. Med. 2008.

to increase, highlighting the growth in the number and severity of poisonings and the need for toxicological expertise in clinical settings.[6] It is estimated that every dollar invested in the poison center system saves $13.39 in medical costs and lost productivity, for a total savings of more than $1.8 billion every year. Of that $1.8 billion, the federal government saves approximately $662.8 million in avoided medical care costs.[7] In addition to providing the public and health care providers with treatment advice on poisonings, a second critical function of the poison centers is the collection of poison exposure and disease surveillance data. Multiple federal agencies, including the CDC, Consumer Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, and Substance Abuse and Mental Health Services Administration, use poison center local and national data for public health surveillance. This surveillance includes timely identification, characterization, or ongoing tracking of outbreaks and other public health threats. Poison centers also provide case triage and management advice for specific public health events. For example, the AAPCC is partnering with the CDC's Influenza Coordination Unit to create a coordinated national network that will provide telemedicine services during a severe influenza pandemic to: (1) improve access to antiviral prescriptions for ill persons; (2) provide an alternative to face-to-face provider encounters; and (3) reduce medical surge and increase appropriate use of medical resources. It is anticipated that, once created, this network may also be capable of providing services during other public health emergencies. Additionally, the Office of National Drug Control Policy ("ONDCP") and the Department of Justice's Drug Enforcement Administration ("DEA") have

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[6] Bronstein AC, Spyker DA, Cantilena LR Jr, et al. 2011 annual report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th annual report. Clin. Toxicol. (Phila). 2012; 50:911-1164.

[7] Value of the Poison Center System: Lewin Group Report for the American Association of Poison Control Centers. 2011.

used poison center local and national data to monitor the rise in the abuse of synthetic drugs, support the Synthetic Drug Abuse Prevention Act of 2012, and formulate the National Drug Control Policy of 2012.

Additionally, poison centers provide public and health care provider education. Poison centers' health educators actively work to change behaviors to reduce poisonings and promote awareness and utilization of poison center services in their communities. An example of this is the Sharing Pills Can Kill campaign to educate teens about the dangers of prescription drug abuse. In recent years, over ninety percent of unintentional poisonings have been caused by prescription drugs, most significantly opioid analgesics. These drugs are implicated in more poisoning deaths than heroin and cocaine combined. Among the actions outlined in the ONDCP's prescription drug abuse prevention plan, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, are educating parents, youth and patients about the dangers of abusing prescription drugs, educating prescribers about the safe and appropriate use of these drugs, and developing convenient and environmentally responsible medication disposal programs. Poison centers are active partners in these efforts and both the poison centers and the national poison center network have participated in the National Prescription Drug Take Back events sponsored by the DEA. Poison centers also provide training and programs in clinical toxicology for medical schools and diverse health care professionals to help clinicians better manage poisoning and overdose cases.

Data collected in real-time from the nation's network of poison centers are an important source of information for federal agencies for the detection, monitoring of, and response to public health and environmental emergencies involving toxic exposures and pandemics, as well as contamination of the air, water, pharmaceutical, or food supply. This has been demonstrated

in the recent national emergencies such as the Gulf oil spill, the H1N1 outbreak and the Fukushima Nuclear Accident where the nation's poison centers were called upon to serve as a key source of healthcare information and surveillance by relevant state and federal agencies.

In the event of a terrorist event, poison centers will be relied upon as a critical resource for accurate medical information and public health emergency response concerning the treatment of patients who have had exposures to a chemical, radiological, or biological agent.

As tens of millions of American families are well aware, the nation's network of accredited poison centers is critically important to avoid unnecessary poisoning deaths and injuries, and as a direct result of this federal-state-local-private sector partnership, health care in the United States is delivered more effectively and efficiently to urban and rural areas alike, resulting in billions in annual health care cost savings to all.

Thank you again for this opportunity to highlight the value and importance of the national poison center program. We strongly support the proposed Terry-Engel poison center program reauthorization legislation before the subcommittee today.

Mr. PITTS. I now recognize Dr. Stack, 5 minutes for an opening statement summary.

STATEMENT OF STEVEN J. STACK

Mr. STACK. Thank you, Mr. Chairman. My name is Steven Stack, an emergency physician from Lexington, Kentucky, and the immediate past chairman of the board of trustees of the American Medical Association. To begin, thank you, Chairman Pitts, Ranking Member Pallone, and members for convening to examine public health legislation to help local communities. The AMA appreciates the opportunity to provide our views on H.R. 3528, the National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013. Reauthorization and full appropriations for NASPER are urgently needed to ensure that physicians across our Nation have this critical tool to combat the scourge of prescription drug abuse while ensuring that patients in pain are relieved of their suffering.

The personal and economic costs of prescription drug abuse far outweigh the annual appropriations of H.R. 3528. One study puts the potential overall cost of prescription drug abuse at more than $70 billion a year. The escalating cost of diverted prescription drugs to the overall health care system and the financial impact to the rest of the economy are enormous. The human cost and personal tragedies that could be averted with the help of NASPER are no less profound.

Since 2005, the AMA, along with many other health care stakeholders, have supported NASPER as an essential resource to combat prescription drug abuse and diversion. Unfortunately, the appropriations to fully fund, modernize, and optimize NASPER prescription drug monitoring programs, or PDMPs have not kept pace with the escalation in abuse and diversion.

Physicians struggle firsthand with this epidemic and fully understand the human cost and toll it takes on families and entire communities. It is a formidable challenge. We have an ethical obligation to treat patients with pain, and also to identify inappropriate drug seekers in order to prevent abuse, overdose, and death. This is not easy. In fact, it is often downright difficult. Physicians face many barriers in their efforts to maintain a balance.

The AMA agrees with other impacted stakeholders that this problem requires a multi-pronged coordinated strategy. We support robust implementation of a combination of Federal and State policies to address both the supply and demand side of this epidemic. Modernized and fully interoperable PDMPs are a key component of these efforts. Though nearly a decade has passed since NASPER was enacted, the full promise has not been achieved.

In theory, PDMPs were to provide reliable and actionable clinical information to physicians in State public health agencies. In reality, although $60 million was authorized over a 5-year period, it was not until 2009 that Federal funds were appropriated under NASPER to support the State adoption of PDMPs.

H.R. 3528 is urgently needed now. The vast majority of physicians still don't have access to reliable real-time information about controlled substance prescriptions patients have obtained and filled from other prescribers. In fact, it is only in the past couple of years

that most States have finally passed legislation establishing PDMPs. Even now, the majority of PDMPs still are not real-time, interoperable, or available at the point of care as a regular part of physician workflow. In far too many States, PDMPs remain underfunded, understaffed, and technologically inadequate. Recent years, a financial belt tightening within States has led to anemic funding, and in some cases, defunding of PDMPs, even as this public health scourge ravages our communities. We must do better.

To be helpful, it is essential that PDMPs are easy to use and provide reliable information to guide sound clinical decisions. When prescription drug monitoring programs support clinical decision making, the efficacy is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers, given reliable PDMP data, altered their prescribing decisions. Accurate PDMP data can directly inform sound clinical decisions, thereby reducing diversion and abuse, while still ensuring that patients receive the care they need.

The AMA is committed to combating prescription drug abuse and diversion. Further, we believe a public health focus is essential to achieve to successful and sustainable solutions. By working together, we can and will resolve this crisis. The AMA appreciates the opportunity to provide our views on the essential role of modernized PDMPs. Action is needed now. I implore you to urgently reauthorize and fully fund NASPER. Thank you.

[The prepared statement of Mr. Stack follows:]

Statement

of the

American Medical Association

to the

Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives

RE: Examining Public Health Legislation to Help Local Communities

November 20, 2013

(202) 789-7481
Division of Legislative Counsel

Statement

of the

American Medical Association

to the

Committee on Energy and Commerce
Subcommittee on Health United States House of Representatives

RE: Examining Public Health Legislation to Help Local Communities

November 20, 2007

The American Medical Association (AMA) appreciates the opportunity to provide our views on H.R. 3528, the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013" (NASPER 2013). In short, passage of NASPER 2013 and full appropriations is urgently needed to ensure that physicians across the country have a critical tool at the point-of-care to combat prescription drug abuse while ensuring patients with legitimate need of pain management continue to have access. Since 2005, the AMA, along with many other stakeholders in the health care community, has supported the National All Schedules Prescription Electronic Reporting Act (NASPER) as an essential resource for individualized clinical decision-making that supports efforts to combat prescription drug abuse and diversion. Unfortunately, the appropriations to fully fund, modernize, and optimize NASPER prescription drug monitoring programs (PDMPs) have not kept pace with the rapid escalation in abuse and diversion of prescription drugs. The AMA continues to work on a number of fronts to combat diversion and drug abuse. We strongly urge immediate passage of H.R. 3528 and full appropriations with a strong emphasis on the public health focus of NASPER.

The AMA has worked with federal and state policymakers to address this growing public health crisis of prescription drug abuse and diversion for many years. At the federal level, the AMA is a founding member of the Alliance to Prevent the Abuse of Medicines (the Alliance), a non-profit partnership of key stakeholders in the prescription drug supply chain—e.g., manufacturers, distributors, pharmacy benefit managers, pharmacies, physicians—established to develop and offer policy solutions aimed at addressing the prescription drug abuse epidemic.

The AMA brings a critical perspective as physicians are on the frontlines of this epidemic and fully understand the human cost and the toll it can take on families and whole communities. We remain committed to continuing our collaboration with other stakeholders to implement effective solutions to rapidly reverse the trends and successfully treat addiction and stop overdose and death. Physicians work hard to balance their ethical obligation to treat patients

with legitimate pain management needs against the need to identify drug seekers and prevent abuse, overdose, and death from prescription drugs. Physicians must confront numerous challenges in their efforts to maintain that balance.

The AMA agrees with all of the impacted stakeholders at the state and federal level that the solution to the prescription drug abuse and diversion problem requires a multipronged, coordinated strategy. We support rapid implementation of a combination of federal and state policies to address both the supply and demand side of this epidemic. Equally important, the AMA and its partners in the medical community have committed resources to promote physician education and awareness, as well as strategies to treat addiction and reduce the incidence of overdose and death. With concerted coordination and team work, this comprehensive approach should substantially improve our ability to stop abuse and diversion and avoid pushing those with opioid addiction to the use of illicit drugs, such as heroin.

A key component of efforts to combating prescription drug abuse, diversion, overdose, and death are modernized, updated, fully interoperable PDMPs. Though nearly a decade has passed since NAPSER was enacted, its full promise has not been achieved. We believe that the enactment of H.R. 3528, along with full appropriations, dramatically improves the odds that physicians will have reliable, high value, patient-specific information at the point-of-care to support appropriate prescribing and treatment for individuals with legitimate pain management needs. We strongly urge Congress to retain the public health focus of NASPER.

Why is H.R. 3528 urgently needed now? First and foremost, the vast majority of physicians still do not have access to reliable, real-time information about prescriptions patients have obtained (and filled) from other prescribers, particularly controlled substances. As a result of years of concerted advocacy and the work of this Committee, NASPER was signed into law in 2005. Although $60 million was authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMPs. In theory, PDMPs were to provide reliable and actionable clinical information to physicians and state public health agencies. It has been only in the past couple of years that most states have finally passed legislation establishing PDMPs. However, the majority of PDMPs are not real-time, interoperable, or available at the point of care as part of physician's workflow. For example, we have learned of one state where the PDMP has one staff person assigned to reconcile potentially overlapping patient records in the PDMP. This can cause significant delay in a physician's access to up-to-date and accurate information.

In instances when prescription drug monitoring programs are available at the point-of-care, with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned. This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances.

Providing physicians with database information that is out-of-date and unreliable cannot enhance or improve their ability to make informed prescribing decisions. Physicians, allied health professionals, and staff are barraged with a sea of clinical and administrative

information and the amount of data and information that they must wade through daily is only projected to grow. It is essential that PDMPs provide reliable and useful information upon which sound clinical decisions can be made.

The AMA has expressed strong support for the reauthorization and full appropriations for prior bills that would have reauthorized NASPER, and that support extends to H.R. 3528, which would provide needed funding and support to modernize existing state-based PDMPs that have a public health focus and provide physicians with a basic tool to make treatment determinations based on patient-specific needs. Until up-to-date PDMP data is provided to physicians as part of the normal flow of information in their practices, patients who are intent on abusing or diverting prescription drugs and who are proficient "doctor shoppers" will still be able to evade detection. Congress should reauthorize NASPER and provide substantial new funding to upgrade and modernize all PDMPs so that states have resources to ensure interstate interoperability and prescriber real-time access at the point-of-care.

In addition to supporting reauthorization of NASPER and full appropriations, the AMA has participated in and supports the current Administration's efforts to identify technical solutions to improve interoperability, enhance communication among state PDMPs, and facilitate integration of PDMP data into physicians' normal work flow.

The AMA also has:

- Expressed strong support for the Administration's and Congress' efforts to ensure that the Veterans Administration (VA) shares prescribing information with relevant state PDMPs and that VA-based prescribers are authorized to consult the state PDMP.
- Urged the Centers for Medicare & Medicaid Services to require Medicare Advantage and Medicare Prescription Drug plan sponsors to work with state PDMPs to coordinate and share prescribing information.
- Supported implementation of the National Association of Boards of Pharmacy software program "InterConnect" that provides Health Information Portability and Accountability Act-compliant interoperability for state PDMPs.

In far too many states, PDMPs remain underfunded and understaffed and are far from achieving a state of technological optimization. The financial belt tightening among states for the past several years has led to anemic funding and, in some cases, defunding of PDMPs while this public health scourge spread and has grown.

An effective, well-funded public health response is needed from all stakeholders. Congress is able to help with much needed funding for PDMP modernization, interoperability, and integration into physician workflow. Just as with illicit drug abuse, prescription drug abuse, overdose, and death cannot be addressed through a singular focus on law enforcement—it will simply change the face of the epidemic from prescription drug abuse to illicit drug abuse, such as heroin. Use of the PDMPs in the hands of physicians and public health officials ensures that individuals who are abusing prescription drugs can be identified by health care providers and are more likely to access treatment and recovery programs. At the same time, it ensures that those with legitimate medical need for pain management and treatment receive it and are not stigmatized.

As an organization dedicated to patient care, the AMA is committed to combating prescription drug abuse and diversion. A public health focus is essential to finding the critical solutions needed to go beyond the current strategies of restriction and limitation that inhibit legitimate patient access to pain treatments.

The personal and economic costs of prescription drug abuse far outweigh the annual appropriations for H.R. 3528. While studies vary—one study puts the potential overall cost of prescription drug abuse at more than $70 billion a year—the Drug Abuse Warning Network reports from 2004 to 2011, the number of emergency room visits for the misuse or abuse of prescription drugs increased by 128 percent. An increase in emergency room visits does not capture the financial impact to the overall health care system of diverted prescription drugs, treatment programs, and costs to other parts of the economy. The human cost and personal tragedies that can be averted with real-time patient specific data at the point-of-care to support clinical decision-making is far more difficult to quantify, but no less significant.

Action is needed now. We urge immediate passage of H.R. 3528.

The AMA appreciates the opportunity to provide our views to the Energy and Commerce Committee on the effective strategies to combat prescription drug abuse and diversion and the essential role of modernized PDMPs. We look forward to working with the Committee and Congress to ensure the proper balance is struck to rapidly reverse the trends of prescription drug abuse, overdose, and death while ensuring patients with legitimate need for pain management and treatment continue to have access.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes Dr. Nagele for 5 minutes for an opening statement.

STATEMENT OF DREW NAGELE

Mr. NAGELE. Chairman Pitts, Ranking Member Pallone, and members——

Mr. PITTS. Is your light on?

Mr. NAGELE. Yes.

Mr. PITTS. Just make sure. OK. Pull it up.

Mr. NAGELE. And members of the Health Subcommittee, thank you for inviting me to testify on reauthorization of the Traumatic Brain Injury Act, H.R. 1098.

My name is Dr. Drew Nagele. I am the executive director of Beechwood NeuroRehab, which serves clients from Pennsylvania, New Jersey, and Delaware. For over 30 years, I have worked with individuals who have brain injury and their families as a licensed psychologist. I serve on the board of the Brain Injury Association of America, and I am also testifying on behalf of the National Association of State Head Injury Administrators and the National Disability Rights Network.

2.4 million Americans of all ages, races, and income levels sustain TBIs each year. The injury can change the way a person can think, move, talk, feel, and act, and can increase the risk for other brain-related diseases and disorders. The TBI Act is a comprehensive law combining research, data collection, prevention, public awareness, consumer advocacy, and service system coordination for this vulnerable and growing population. The law authorizes NIH to conduct basic and applied research, and for CDC to conduct surveillance, prevention, and public education programs. The Health Resources and Services Administration makes grants to States and territories to develop or expand service system capacity based on the specific needs in each State. Currently, 20 States and territories are receiving these grant funds.

Many States work to strengthen screening and identification methods among unserved or underserved persons with brain injury. In Pennsylvania, we are screening prison inmates and connecting them to services and supports when they are released from prison. Minnesota has instituted a similar program, and Virginia is screening its juvenile justice inmates.

Several States use grant funds for TBI-specific training and professional development. In New Jersey, State grant funds were used to train members of the clergy. Grants allow States to coordinate and streamline TBI service systems. In Pennsylvania and Tennessee, we have linked hospitals and schools, and in Alabama we have improved Federal mechanisms for accessing existing services.

Additional State grants have helped leverage resources in other Federal and State programs and nonprofit organizations. Michigan and West Virginia evaluated Medicaid utilization and then applied for home and community-based waivers that are tailored to the needs of individuals with brain injury and are more cost-effective for the State. By far, the most common use of State grants is assisting persons with brain injury and their families through out-

reach, information, education, service coordination, and resource facilitation.

Arizona, Colorado, Idaho, Iowa, Indiana, Massachusetts, Michigan, Missouri, Nebraska, New York, Virginia, West Virginia, and Texas have all used TBI Act grants to outreach to children and youth, active duty military and veterans, Native Americans, older adults, multi-cultural families, and the thousands of civilians who fall through the cracks each year. The TBI Act also authorizes formula-funded grants to protection and advocacy organizations to ensure that people with TBI live full and independent lives. Known as PATBI, this programs helps people navigate complex service systems and investigates instances of abuse and neglect.

Recently, the Disability Rights Network of Pennsylvania represented a client who has a TBI as a result of domestic violence and was being denied appropriate services by her service coordinator. Our P&A helped her change to a new service coordinator, and now she is getting the services she needs.

In this reauthorization, BIAA, NASHIA, and NRDN all recommend the State grant program and the PATBI program be elevated within the Department of Health and Human Services, preferably the Administration for Community Living, to better integrate individuals with brain injury into HHS' aging and disability initiatives.

Now, more than ever, it is imperative that we foster collaboration and maximize the limited resources at both the State and Federal levels. This can only be achieved if we work hand-in-hand with other aging and disability populations. The TBI stakeholders believe elevating the program to ACL is the best way to increase effectiveness and cost efficiency. Thank you.

[The prepared statement of Mr. Nagele follows:]

Testimony Submitted by the

Brain Injury Association of America
National Association of State Head Injury Administrators
National Disability Rights Network

To the House Committee on Energy and Commerce
Subcommittee on Health

November 20, 2013

Chairman Pitts, Ranking Member Pallone, and members of the Health Subcommittee, thank you for giving me the opportunity to testify about the reauthorization of Traumatic Brain Injury Act, H.R. 1098.

My name is Dr. Drew Nagele. I am employed as executive director of Beechwood NeuroRehab, which is based in Langhorne and serves clients primarily from Pennsylvania, New Jersey and Delaware. As a licensed psychologist with training and experience in neuropsychology, I have been working with individuals who have brain injury and their families for over 30 years.

I serve on the Board of Directors of the Brain Injury Association of America and as the elected leader of BIAA's chartered state affiliates, 11 of which receive funding to assist their state agencies in carrying out TBI Act initiatives. I am also testifying on behalf of the National Association of State Head Injury Administrators and the National Disability Rights Network in support of reauthorizing the TBI Act.

According to the Centers for Disease Control and Prevention, there were 2.4 million emergency department visits, hospitalizations, or deaths associated with TBI in the US in 2009. Brain Injury is a leading cause of death and disability that affects persons of all ages, races, and income levels. Any injury to the brain – regardless of type, cause or severity – can change the way a person moves, talks, thinks, feels and acts. TBI can cause epilepsy and increase the risk for Alzheimer's disease, Parkinson's disease and other brain disorders that become more prevalent with age.

The TBI Act of 1996, as amended and reauthorized in 2000 and 2008, is a comprehensive law combining research, data collection, prevention, public awareness, consumer advocacy and service system coordination for this vulnerable and growing population.

The law authorizes the National Institutes of Health to conduct basic and applied research and the CDC to conduct surveillance, prevention and public education programs to prevent TBI and help people better recognize, respond, and recover if an injury occurs. For example, the CDC

has produced a number of reports and guidelines relating to Veterans with TBI, sports concussions, and for educators.

The TBI Act also authorizes the Health Resources and Services Administration (HRSA) to make competitive grants to States and Territories to develop or expand service system capacity to address the unique needs of their citizens as determined by statewide needs and resource assessments.

Currently, 20 States and Territories are receiving grant funds. Many states are working to **strengthen screening and identification methods**, particularly among un-served or under-served portions of the TBI population. For example, starting July 2014, all new admissions to domestic violence shelters in Pennsylvania will be screened for TBI as part of our state's grant project. In Pennsylvania, we're also piloting a program to screen inmates for TBI and to connect those who are leaving prison with brain injury services and supports. Minnesota has instituted a similar program, and Virginia is working in partnership with Virginia Commonwealth University to administer screening in its juvenile justice system.

Several states use grant funds for **TBI-specific training and professional development** for educators, substance abuse and mental heath service programs, child care providers and other professionals. For example, in New Jersey, state grant funds were used to train members of the clergy.

Grant funds allow states to **coordinate and streamline service systems** such as improving linkages between hospitals and schools as has been done in Pennsylvania and Tennessee and to improve referral mechanisms to existing brain injury resources as is the case in Alabama.

Additionally, state grants have helped **leverage resources in other federal and state programs and nonprofit organizations**. For example, Michigan and West Virginia have both used grant funds to evaluate Medicaid utilization, leading to successful proposals for Home and Community-Based Services Waivers and other funding mechanisms that are tailored to the needs of individuals with brain injury and are more cost-effective for the state.

By far, the most common use of state grants is to **assist persons with brain injury and their families** through outreach, information, education, service coordination, and resource facilitation. After a life-altering, often devastating, injury, individuals and families need considerable help in navigating the complex maze that makes up state service systems. Grant funding in Arizona, Colorado, Idaho, Iowa, Indiana, Massachusetts, Michigan, Missouri, Nebraska, New York, Virginia, West Virginia, and Texas has supported outreach to children and youth, active duty military and Veterans, Native Americans, older adults, multi-cultural families and the thousands of civilians who fall through the cracks because of TBI.

The TBI Act also authorizes HRSA to make formula-funded grants to Protection and Advocacy organizations to ensure that people with TBI live full and independent lives free from abuse, neglect, and financial exploitation. Known as Protection and Advocacy for Traumatic Brain

Injury, the PATBI program helps people with brain injury navigate complex service systems within their state and investigates instances of abuse and neglect that, unfortunately, occur far too often in this population.

Recently, the Disability Rights Network of Pennsylvania, which is the designated protection and advocacy organization in my state, represented a client who has a TBI as a result of domestic violence and was being denied appropriate services by her service coordinator. Our P&A helped her change to a new service coordinator, and now she is getting the services she needs and is being treated with dignity and respect.

In this reauthorization, the Brain Injury Association of America, the National Association of State Head Injury Administrators, and the National Disability Rights Network recommend the committee elevate the State Grant Program and the PATBI Program within the Department of Health and Human Services.

We believe that by elevating these programs within HHS, preferably to the Administration for Community Living, individuals with brain injury would be better integrated into the department's aging and disability initiatives. For example, moving the State and P&A grant programs would:

- Promote collaboration on fall-related TBIs among older adults,
- Support collaborations between HHS and the Department of Veterans Affairs in developing and implementing home and community-based service and support initiatives,
- Assure that families who are primary caregivers are included in the Lifespan Respite Care Program; and
- Coordinate and strengthen services for individuals with TBI of all ages who may also be eligible for services provided through other disability systems.

We're specifically recommending the state grant and protection and advocacy grant programs authorized by the TBI Act be moved to the ACL because that agency was created to address needs of individuals with disabilities across the lifespan by combining and coordinating services and resources within the Administration on Aging, the Administration on Intellectual and Developmental Disabilities, and the Office of Disabilities.

Now more than ever, it is imperative that we foster collaboration and eliminate potential for duplication in order to maximize the limited resources at both the state and federal levels. This can only be achieved if we work hand-in-hand with other aging and disability populations. The TBI Stakeholders believe the best way to increase effectiveness and efficient is to elevate the state and protection and advocacy grant programs to the Administration for Community Living.

With your help, advocates, state agency administrators, researchers and clinicians can continue to work together to improve the lives of individuals with brain injury. Thank you for giving me the opportunity to testify today. I am happy to answer any questions you may have.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes Dr. McCabe, 5 minutes for an opening statement.

STATEMENT OF EDWARD R.B. MCCABE

Mr. MCCABE. Good afternoon, Chairman Pitts, Ranking Member Pallone, and members——

Mr. PITTS. Is your mic on? There you go.

Mr. MCCABE. Good afternoon. And thank you. My name is Dr. Edward McCabe, and I am senior vice president and chief medical officer for the March of Dimes Foundation, a unique partnership of scientists, clinicians, parents, and volunteers working to prevent birth detects, preterm birth, and infant mortality. I appreciate this opportunity to testify today on newborn screening, one of the great public health victories of the 20th Century and one which continues to save infants lives every day. Newborn screening is a critically important and highly effective public health program for testing every newborn for certain genetic, metabolic, hormonal, and functional conditions not authorize apparent at birth.

Approximately one in every 300 newborns has a condition that can be detected through screening. Newborn screening detects conditions that, if left untreated, can cause disability, developmental delay, illness, and even death. If diagnosed early, many of these disorders can be managed successfully, which not only reduces the physical burden of disease but can also help to reduce the associated economic burden on families, communities, and the government.

This year, our Nation is celebrating the 50th Anniversary of newborn screening. The March of Dimes is deeply proud of our decades' long history of funding research that has led or contributed to the development of numerous newborn screening tests. Together, these tests have allowed us to preserve the health and wellbeing of thousands of children.

The remarkable progress of newborn screening over the past 2 decades persuaded Congress to pass a Newborn Screening Saves Lives Act in 2008. The law renewed and updated various programs that underpin States' newborn screening efforts as well as the Secretary's Advisory Committee on Heritable Disorders. That law expired at the end of fiscal year 2013 and is due for a 5-year renewal. Passage of the Newborn Screening Saves Lives Reauthorization Act is essential to the continued success of newborn screening programs across our Nation.

Most importantly, reauthorization will ensure the uninterrupted continuation of the Secretary's Advisory Committee on Heritable Disorders and its work. Maintaining and updating the recommended uniform screening panel that States use to adopt and implement new conditions is vital and ongoing and planned evidence review should not be delayed. The Newborn Screening Saves Lives Reauthorization Act also extends important programs at HRSA, CDC, and NIH, including Seven Genetics and Newborn Screening Regional Collaborative Groups and the National Coordinating Center, which improves the availability, accountability, and quality of genetic services and resources for individuals with genetic conditions; the Critical Congenital Heart Disease Newborn

Screening Demonstration product program, a program to support the development, dissemination, and validation of screening protocols and newborn screening infrastructure for point-of-care screening specific to congenital heart defects; Babies First Test, a national educational resource center for newborn screening, the Newborn Screening Technical Assistance and Evaluation Program, or NewSTEPs, which serves as a technical assistant program for State newborn screening systems; the Newborn Screening Quality Assurance Program, a comprehensive CDC program devoted to ensuring the accuracy of newborn screening; and the Hunter Kelly Research Program at the NIH, which supports grants and contracts to develop and improve technologies related to newborn screening.

Today, 42 States and the District of Columbia require screening for at least 29 of the 31 treatable core conditions. Millions of babies have been screened for dozens of disorders, and in thousands of cases, the health and well-being of those children has been preserved. Newborn screening represents a model Federal-State public health partnership that has produced extraordinary improvements in child health.

We must not allow this vital public health effort to falter. On behalf of over 3 million March of Dimes volunteers and countless other organizations and families, I urge the members of this subcommittee to cosponsor and support H.R. 1281, the Newborn Screening Saves Lives Act, and the committee to report the legislation this fall. We look forward to working closely with the committee and chamber leadership to ensure it can be passed as soon as possible by both the House and the Senate.

Thank you for your attention to this vitally important child health issue. The March of Dimes stands ready to assist you in ensuring that newborn screening programs will continue to protect the health and well-being of newborns for many years to come. Thank you.

Mr. PITTS. The Chair thanks the gentleman.

[The statement of Mr. McCabe follows:]

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Testimony of Edward R.B. McCabe, M.D., Ph.D.
Senior Vice President and Chief Medical Officer, March of Dimes Foundation

Energy and Commerce Subcommittee on Health Hearing
Examining Public Health Legislation to Help Local Communities

Wednesday, November 20, 2013

Good afternoon Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee. My name is Dr. Edward McCabe, and I am Senior Vice President and Chief Medical Officer for the March of Dimes Foundation, a unique partnership of scientists, clinicians, parents, members of the business community and other volunteers affiliated with 52 chapters and over 200 divisions in every state, the District of Columbia and Puerto Rico. I appreciate this opportunity to testify today on newborn screening, one of the great public health victories of the 20th century, and one which continues to save infants' lives every day.

The March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to support research and services related to polio. Today, the Foundation works to improve the health of women, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education and advocacy. In 1998, the March of Dimes established its Global Programs division to extend its mission overseas through partnerships with countries to deliver interventions directed at reducing birth defects and preterm birth.

Background

Newborn screening is a critically important and highly effective public health program for testing every newborn for certain genetic, metabolic, hormonal and functional conditions not otherwise apparent at birth. Approximately 1 in every 300 newborns has a condition that can be detected through screening. Newborn screening detects conditions that, if left untreated, can cause disabilities, developmental delays, illnesses or even death. If diagnosed early, many of these disorders can be managed successfully, which not only reduces the physical burden of disease but can also help to reduce the associated economic burden on families, communities, and government.

Since the mid-1960s, the success of newborn screening programs has led to routine testing for the over four million infants born in the United States each year. The Centers for Disease Control and Prevention (CDC) estimates that each year over 6,000 newborns are diagnosed as having a treatable metabolic condition and another 12,000 are found to have hearing impairment that requires follow up. The majority of newborn screen tests are performed using a single sample of a few drops of blood from the newborn's heel, usually taken in the hospital 24 to 48 hours after birth. Hearing screening and screening for critical congenital heart disease (CCHD) are performed with non-invasive devices; hearing screening utilizes a handheld device held near the infant's ear, while pulse oximetry is used to test for CCHD by way of a small probe that clips onto a newborn's hand or foot.

History of Newborn Screening

This year, our nation is celebrating the 50th anniversary of newborn screening; however, the program's origins reach back much earlier. In 1959, after the March of Dimes had led our nation to the successful development of the Salk and Sabin polio vaccines and refocused our mission on birth defects prevention,

we initiated discussions about newborn screening on a large scale as a means to detect and prevent the catastrophic consequences of metabolic conditions such as phenylketonuria (PKU). This led to a grant to Dr. Robert Guthrie to support his development of a simple and effective population-based screening test for PKU. Dr. Guthrie's work demonstrated conclusively that identifying infants with PKU and immediately beginning a low-protein diet could completely avert the otherwise devastating developmental disabilities PKU causes. These results were so dramatic that the state of Massachusetts mandated PKU screening for all infants in 1968, beginning the modern era of newborn screening.

Subsequently, the March of Dimes funded research into tests for other genetic and metabolic diseases in newborns as we promoted newborn screening as a central component of newborn medical care. The Foundation is deeply proud of our decades-long history of funding research that has led or contributed to the development of numerous newborn screening tests, including those for congenital adrenal hyperplasia, biotinidase deficiency, and others. Together, these tests have allowed us to preserve the health and wellbeing of thousands of children.

As more tests became available, however, a patchwork developed in which some states screened for numerous disorders and other very few. In 2000, the March of Dimes led the way in proposing a national standard for newborn screening which included a core list of 9 disorders, with provisions for expanding the list as science and technology evolved. At the same time, the March of Dimes and others in the policy community began working with Congress to bring new attention and focus to this rapidly developing field. We worked to identify policy changes that would allow the federal government to assist states in evaluating new tests and determining whether to include them in their screening panels. The landmark Children's Health Act of 2000 (P.L. 106-310) included two vital provisions that advanced newborn screening policies. The law created the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children to provide expert evaluations of new tests and consideration of challenges in the field. It also established federal grants to enhance and evaluate state newborn screening programs, allowing them to develop and implement best practices.

In August 2004, the American College of Medical Genetics (ACMG) submitted a report requested by the Health Resources and Services Administration (HRSA) setting out proposed nationwide standards for state newborn screening programs. The report listed 29 core treatable disorders that should be targeted directly and an additional 25 secondary conditions for which test results should be reported. These secondary disorders were not directly targeted by newborn screening because they did not yet have documented treatments or because there was limited knowledge of their natural history. Their presence would be revealed, however, in the course of screening for the core conditions. The ACMG recommendation to screen all newborns for 29 core conditions was endorsed by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children as well as the March of Dimes in 2005.

The federal Recommended Uniform Screening Panel (RUSP) gave advocates a powerful tool to press state legislatures to adopt this consistent set of tests. The March of Dimes led a grassroots advocacy campaign to secure adoption of the recommended uniform panel in every state, issuing annual report cards to document progress. And it was spectacularly effective: in 2004, only 21 states screened for at least nine of the recommended conditions, but just four years later all but two states were screening for at least 21.

Since 2010, the Advisory Committee, with the Secretary's approval, has added two new conditions to the Recommended Uniform Screening Panel: severe combined immunodeficiency (SCID) and critical congenital heart disease (CCHD). A third condition, Pompe Disease, should be decided by the Secretary at the end of this month. This year alone, the March of Dimes and allies like the American Heart Association have advocated successfully for 24 states to add CCHD to their newborn screening panels. This system of review and recommendations by the expert Advisory Committee, approval and dissemination by the HHS Secretary, and adoption by the states continues to work effectively to ensure that tests are evaluated appropriately and then adopted in a timely fashion to protect the health of our nation's infants.

The Newborn Screening Saves Lives Act

The remarkable progress of newborn screening over the past two decades persuaded Congress to pass the Newborn Screening Saves Lives Act in 2008 (P.L. 110-204). The law renewed and updated various programs that underpin states' newborn screening efforts as well as the Secretary's Advisory Committee. Most notably, it codified the authority of the Secretary of Health and Human Services to establish the Recommended Uniform Screening Panel and to accept or reject the Advisory Committee's recommendations to add conditions to the RUSP. The law expired at the end of Fiscal Year 2013 and is due for a five-year renewal.

The March of Dimes is deeply grateful to Representatives Lucille Roybal-Allard and Mike Simpson and Senators Kay Hagan and Orrin Hatch for introducing H.R. 1281 and S. 1417, the Newborn Screening Saves Lives Reauthorization Act. Reauthorization is critical to ensuring the continuation of the most accurate and comprehensive screening available to our nation's children.

Passage of the Newborn Screening Saves Lives Reauthorization Act is essential to sustaining the success of newborn screening programs across our nation. Most importantly, reauthorization will ensure the uninterrupted work of the Secretary's Advisory Committee on Heritable Disorders. The Advisory Committee's charter expired in April of this year, and it was only through the timely action of Health and Human Services Secretary Kathleen Sebelius that it was extended on a discretionary basis for up to an additional two years. Maintaining and updating the Recommended Uniform Screening Panel that states use to adopt and implement new conditions is vital. Ongoing and planned evidence reviews should not be delayed.

The Newborn Screening Saves Lives Reauthorization Act also extends important grant programs at the Health Resources and Services Administration, Centers for Disease Control and Prevention and National Institutes of Health, including:

- Seven Genetics and Newborn Screening Regional Collaborative Groups (RCs) and a National Coordinating Center (NCC) funded by HRSA, which improve the availability, accessibility, and quality of genetic services and resources for individuals with genetic conditions using a regional approach to addressing maldistribution of genetic services and resources. Special emphasis is given to underserved populations and those families and providers in rural areas. The RCs include all states, U.S. Territories and the District of Columbia.
- The Critical Congenital Heart Disease (CCHD) Newborn Screening Demonstration Program, a three-year HRSA grant designed to support the development, dissemination and validation of screening protocols and newborn screening infrastructure for point of care screening specific to CCHD. CCHD presents special challenges to implementation since it is not tested with the blood spot.
- *Baby's First Test*, a national educational resource center for newborn screening presently operated by Genetic Alliance under a HRSA grant. *Baby's First Test* informs and empowers families and healthcare providers throughout the newborn screening experience.
- The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) funded by HRSA, which serves as a technical assistance program for state newborn screening systems.
- Newborn Screening Quality Assurance Program (NSQAP), a comprehensive CDC program devoted to ensuring the accuracy of newborn screening. NSQAP is the only comprehensive program in the world devoted to ensuring the accuracy of newborn tests. In 2012, the program guaranteed the quality of newborn testing in more than 550 laboratories worldwide, and assured identification of between five and six thousand infants with treatable diseases who might have otherwise died or become severely disabled.
- The Hunter Kelly Research Program, which supports numerous grants and contracts to develop and improve technologies related to newborn screening. Through the Hunter Kelly Newborn Screening Research Program, the Eunice Kennedy Shriver National Institute of Child Health and Human Development also funds the Newborn Screening Translational Research Network, a resource for investigators engaged in newborn screening related research.

Conclusion

Today, 42 states and the District of Columbia require screening of at least 29 of the 31 treatable core conditions. Millions of babies have been screened for dozens of disorders, and in thousands of cases, the health and wellbeing of those children has been preserved. Newborn screening represents a model federal-state public health partnership that has produced extraordinary improvements in child health.

We must not allow this vital public health effort to falter. Our most immediate challenge is to preserve and renew the Newborn Screening Saves Lives Act. On behalf of

over 3 million March of Dimes volunteers and countless other organizations and families, I urge members of this Subcommittee to cosponsor and support H.R. 1281 and the Committee to report the legislation. We look forward to working closely with the committee and chamber leadership to ensure it can be passed as soon as possible in both the House and the Senate. Furthermore, although beyond the jurisdiction of this Committee, I urge Congress and the Administration to agree on a balanced approach to deficit reduction that protects investments in programs such as newborn screening. Authorization bills are only effective insofar as funding is appropriated to implement their provisions.

Newborn screening has improved and saved the lives of countless thousands of affected children. Thank you for your attention to this vitally important child health issue. The March of Dimes stands ready to assist you in ensuring that newborn screening programs will continue to preserve the health and wellbeing of newborns for many years to come.

Mr. PITTS. Now recognize Ms. Smith, 5 minutes for an opening statement.

STATEMENT OF PATRICIA V. SMITH

Ms. SMITH. Thank you, Mr. Chairman and committee members. I appreciate the opportunity to testify on the establishment of Lyme and Tick-Borne Diseases Advisory Committee. In 2009, the CDC indicated that Lyme surpassed HIV in incidents, and that was followed by a 2013 announcement confirming a 10-fold underreporting of Lyme cases, estimating 300,000 Lyme cases annually. A 2001 NIH-sponsored study found the impact of Lyme on physical health status was at least equal to the disability of patients with congestive heart failure or osteoarthritis and, was greater than those with type II diabetes or recent myocardial infarction. If you couple those facts with Lyme spreading worldwide now to 80 countries and the discovery of many new emerging tick-borne pathogens carried by many different ticks, then the passage of H.R. 610 is long overdue.

Other tick-borne diseases in the U.S. include anaplasmosis, babesiosis, bartonellosis, ehrlichiosis, Rocky Mountain Spotted fever, Colorado tick fever, Q fever, tick paralysis, tularemia, Powassan encephalitis, STARI, which is a Lyme-like disease carried by a different tick, Rickettsia parkeri—parkeri, excuse me, Ricketsiosis found increasingly along the Gulf Coast and in the South, Borrelia miyamotoi, which was an organism that produced disease in Russia, the first cases, and now it has been found here, and Eschar-associated illness, Ricketsia species 364D in the Pacific region, and a newly-discovered tick-borne virus in Missouri called Heartland.

So, my education on Lyme began almost 30 years ago as a New Jersey Board of Education member whose district had a large number of students and staff out with the disease. At that time, only a few ticks were recognized as major health threats to humans. Now the list includes Ixodes scapularis, which is the deer or black-legged tick you probably know, Amblyomma americanum, the lone start tick, Dermacentor variabilis, the American dog tick, Dermacentor andersoni, the Rocky Mountain wood tick, Ixodes pacificus, which is the western black-legged tick, Amblyomma maculatum, the Gulf Coast tick, and Dermacentor occidentalis, the Pacific Coast tick.

Now, one tick bite can produce more that one disease at the same time. My Lyme work, including 17-plus years as president of the volunteer-run national nonprofit Lyme Disease Association keeps me in close contact with patients nationwide. Lyme's complexity and difficulty in diagnosis have exacerbated the plight of patients and their families, many of which contain more than one Lyme victim. Medical bills rise, jobs are lost, education is interrupted. Children are at the highest risk of acquiring Lyme, and based on CDC's Lyme reported case numbers from 2001 to 2010 by age, the LDA estimates 37 percent of reported cases were children. So, if you use 1990 through 2011 CDC reported numbers and you adjust that for the 10-fold underreporting, we then found that 1,599,000—excuse me, 1,590,499 children have developed Lyme

over that time period, and unfortunately, there are probably more children that were diagnosed, but they weren't included in that CDC surveillance figure because that is a very narrow surveillance criteria not meant for clinical diagnosis.

A 2001 Columbia study showed children with Lyme had significantly more psychiatric disturbances and cognitive deficits, even after they were controlled for anxiety, depreciation, and fatigue. So Lyme in children may be accompanied by long-term neuropsychiatric disturbances resulting in psycho, social, and academic impairment. Parents indicated 41 percent of children had suicidal thoughts. 11 percent had made a suicide gesture.

Early intervention and appropriate treatment are the answers for Lyme patients to prevent development of chronic disease, also known as Post Treatment Lyme Disease, late disseminated Lyme disease, persistent Lyme, Post Lyme Disease Syndrome, et cetera. The discussions continue on the justification for various terms for chronic Lyme, but we can't allow semantics to eclipse the need for research on chronic Lyme, the area producing the most human suffering, but yet it is receiving the least research funding.

According to a new Columbia study, based upon the 10-fold underreporting and 10 percent of newly infected and treated patients developing symptoms, which persist for more than 6 months, the actual incidents of new chronic Lyme cases, which they call Post Treatment Lyme Syndrome, is 30,000 annually for chronic Lyme development.

Many major health threats, including chronic fatigue, have an advisory committee. Lyme doesn't, placing patients and advocates at a great disadvantage. We have lobbied for a research agenda, which includes more effective treatments that are diagnostic, including detection of active infection. Borellia Burgdorferi was recognized to cause Lyme almost 33 years ago, yet the two-tier testing system endorsed by CDC, though it is very specific for Lyme, 99 percent and gives few false positives, the tests have a uniform low sensitivity, 56 percent, meaning 88 out of 200 patients with Lyme are missed.

Mr. PITTS. Summarize, please.

Ms. SMITH. Excuse me?

Mr. PITTS. Your time has expired. Could you summarize?

Ms. SMITH. Oh, I am sorry. I was so busy, I didn't realize. I am sorry, Mr. Chairman. Thank you.

Mr. PITTS. Thank you.

[The prepared statement of Ms. Smith follows:]

Testimony before US House of Representatives Energy & Commerce Health Subcommittee

Patricia V. Smith, President, Lyme Disease Association, Inc. (LDA)

Chairman Pitts and Committee Members,

Thank you for allowing me to testify on the need to establish an advisory committee on Lyme disease to ensure that government resources are being appropriately used to move forward the field of science and treatment in an area that is fraught with political, scientific, and medical obstacles, yet is dominating discussion on the worldwide stage. In 2009, the Centers for Disease Control & Prevention (CDC) indicated that Lyme surpassed HIV in incidence followed by a 2013 announcement confirming a 10-fold under-reporting of Lyme cases, estimating 300,000 Lyme cases annually. A 2001 National Institutes of Health (NIH) sponsored study found that the impact of Lyme disease on physical health status was at least equal to the disability of patients with congestive heart failure or osteoarthritis, was greater than those observed in type II diabetes or in recent myocardial infarction, and chronic pain contributing to impairment was similar to that reported by patients with osteoarthritis.i[1] Couple those facts with Lyme spreading worldwide to 80 countries and the discovery of many newly emerging tick-borne pathogens being carried by many different ticks, then the passage of HR 610 is long overdue.

The LDA just revised its comprehensive education and prevention brochure, LymeR Primer, which went from featuring 7 tick-borne diseases (TBD) in 2009 to 15 diseases. Besides Lyme disease, there are at least 15 other TBD of concern in the US: anaplasmosis; babesiosis, bartonellosis; ehrlichiosis; Rocky Mountain Spotted fever; Colorado tick fever; Q fever; tick paralysis; tularemia; Powassan encephalitis; STARI, a Lyme-like disease often with the same rash, transmitted by a lone star tick bite, pathogen cause unknown, but may be a bacteria similar to the Lyme bacteria; *Rickettsia parkeri Ricketsiosis* found increasingly along the Gulf Coast and

in the South; *Borrelia miyamotoi*, a tick-borne bacteria which had been producing disease outside the US, now found in the US; newly found *Ricketsia* species 364D in the Pacific Region; and a newly discovered tick-borne virus in Missouri, Heartland, carried by the lone star tick.ii[2] One tick-bite can give someone more than one disease.

My education on Lyme began almost 30 years ago as a NJ Board of Education member whose district had a large number of students and staff out with Lyme disease. Then, only a few US ticks were recognized as major health threats to humans. Now, many ticks in the US are causing more human diseases, ticks including *Ixodes scapularis* (deer, black legged), *Amblyomma americanum* (lone star), *Dermacentor variabilis* (American dog), *Dermacentor andersoni* (Rocky Mt. wood), *Ixodes pacificus* (western black legged), *Amblyomma maculatum* (Gulf Coast), and *Dermacentor occidentalis* (Pacific Coast).

My Lyme work, including 17+ as president of the national volunteer-run non-profit Lyme Disease Association (LDA), has kept me in close contact with patients nationwide. The complicated nature of Lyme disease, the difficulty in diagnosis, and lack of recognition by some in the medical community have exacerbated the plight of patients and their families, many of which contain more than one Lyme victim. Medical bills rise; jobs are lost; education is interrupted. Divorce is not an uncommon result in these families, further complicating the picture. Often, the families are forced to seek government help, government which is already burdened with more debt than it is able to handle.

Children have always been at the highest risk of acquiring Lyme disease. Based on CDC's Lyme reported cases numbers from 2001-2010 by age, LDA estimated that 37% of reported cases were

children. Using 1990-2011 CDC reported numbers adjusted for 10-fold underreporting, LDA found that 1,590,449 children have developed Lyme disease over that period. Many more children were probably clinically diagnosed but not included in the CDC surveillance figure, which uses a strict reporting definition not meant for clinical diagnosis. These are children who often go on to develop chronic Lyme disease— who often miss months/years of school and have their childhood destroyed. Showering, walking, talking, thinking can be a problem, and serious pain is a daily challenge. A 1998 Columbia University study documents improvement in IQ of 22 points in a 16 year-old after IV treatment for Lyme disease.iii[3]

A 1992 CDC/NJ Department of Health study in NJ of 64 school children with Lyme showed that the median duration of Lyme at time of interview was 363 days; the median number of days the illness was said to have significantly affected normal activities was 293; the mean number of total school days lost was 140; the mean duration of home instruction, 153 days. Only 26% of children under study were said to have fully recovered.iv[4]

The direct medical costs per case incurred by 54 case-patients totaled $5.2 million, $8.7 million in CPI adjusted 2013 dollars.v[5] The mean estimate was $96,569 ($274,412-2013); and costs of $100,000 ($166,891-2013) or greater were incurred by more then 1/5 of children. Some indirect costs were assessed totaling about $15,000 ($ 25,034- 2013) due to lost time caring for patient and parents' lost time transporting children to medical treatment.

A 2001 Columbia study showed children with Lyme disease had significantly more cognitive and psychiatric disturbances. Cognitive deficits were still found after controlling for anxiety, depression, and fatigue. Lyme disease in children may be accompanied by long-term

neuropsychiatric disturbances, resulting in psychosocial and academic impairments. Regarding depression, parents indicated that 41% of children with LD had suicidal thoughts, 11% had made a suicide gesture.vi[6]

Early intervention and appropriate treatment are the answers for patients with Lyme to prevent the development of chronic Lyme disease, aka, Post Treatment Lyme Disease, late disseminated Lyme, persistent Lyme, Post Lyme Disease Syndrome, etc. While discussions continue on the justifications for the various terms used for chronic Lyme disease, we cannot allow the semantics to eclipse the need for research on chronic Lyme, the area producing the most human suffering and receiving the least research funding. According to a new Columbia University Lyme study, based upon 10-fold underreporting and on 10% of newly infected and treated patients developing symptoms that persist for more than 6 months, "the actual incidence of new chronic cases (PTLS) is…30,000." vii[7]

Currently, many major health threats including chronic fatigue have an advisory committee. Lyme disease does not, placing its patients and advocates at a great disadvantage. We have lobbied for a research agenda which includes more effective treatments for Lyme and other TBD and better diagnostics, including detection of active infection. *B. burgdorferi* was recognized in 1981 to cause Lyme, almost 33 years ago, yet the two-tier testing system endorsed by CDC is very specific for Lyme disease (99%), so it gives few false positives, but according to some sources, the tests have a uniformly low sensitivity (56%)— missing 88 of every 200 patients with Lyme disease.viii[8] Yet HIV was identified as the cause of AIDS in 1984, and tests were developed within a few years after and are 99% sensitive and specific.ix[9] Moreover, Lyme has not attracted industry funding for treatment approaches, which has allowed patients to develop

severe mental and physical disabilities from the disease without help from science. There is also a need for educating doctors and the public about the state of the science regarding these diseases.

The above agenda requires the establishment of a venue where government agencies working on diverse aspects of tick-borne diseases (e.g., CDC surveillance, testing; NIH research funding-clinical trials, as well as basic and translational research; FDA drug, vaccine and device approvals; USDA research into natural tick prevention strategies; EPA tick prevention strategies) can present their activities, submit their proposed TBD agenda, and receive input from committee members who represent a wide variety of stakeholders with diverse scientific viewpoints on development of new diagnostics, treatment methods, and prevention strategies. Utilizing this format, government would ensure its agencies were providing the most judicious use of human and financial resources for Lyme and TBD. Using an already established federal advisory committee format ensures that the committee is only advisory in nature – committee members would not control nor dictate agency agendas, a concern that has been expressed by an outside group in the past. However, those agencies should not be insulated from the public input and diverse scientific viewpoints this committee would provide in shaping an agenda and ensuring the wise use of tight federal dollars, which are provided by taxpayers. Another concern might be whether an advisory committee is worth the costs, including time, to support the operation of the committee. In the case of Lyme disease, the history of the past decades should lead to an easy yes.

One does not have to be a scientist to realize that it is premature and unwise to preclude further clinical trials studying a broader range of treatment regimens when there are numerous major and

significant aspects of the bacteria's known pathophysiology which have not been accounted for in studies conducted to date, when there are still many unknowns in that pathophysiology, and when we are learning more every day. While our knowledge of the pathophysiology of the bacteria continues to evolve, we must be open to additional clinical trials to document and establish better treatment regimens. There is preliminary evidence for more effective regimens, and a specific forum for open dialogue can help ensure we move forward and don't get waylaid.

An open dialogue also could only improve the process of utilizing the pool of competent researchers- not in any manner that would interfere with established fair and open processes for grant-making, but only to increase awareness. It's a fact that a small number -a handful- of Lyme researchers have individually received many millions of federal research dollars, many of whom shared the same set of biases and perspectives. Common biases and perspectives are not objectionable if they are based upon the best scientific evidence; open dialogue, information sharing, and transparency can help safeguard the process and the taxpayers' money.

Patients want research which will restore their health. Their voice and the voice of the clinicians must be given the necessary weight to legitimize the research agenda and the research process. Truth in science can be achieved through open discussion with diverse viewpoints in an independent process free from bias and conflicts of interest. The scientific process fails when one side of a debate controls the arena and sets the rules to ensure that its viewpoint prevails.

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i[1] *NEJM*, 7/2001, Mark S. Klempner MD. et al, "Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease"

ii[2] *American Journal of Tropical Medicine and Hygiene*, 7/22/13, Harry M. Savage, PhD et al, "First Detection of Heartland Virus (Bunyaviridae: Phlebovirus) from Field Collected Arthropods"

iii[3] *Psychiatric Clinics of North America*, 1998, Brian Fallon, MD, "The Underdiagnosis of Neuropsychiatric Lyme Disease in Children & Adults"
iv[4] "Economic & Social Costs of Illness Diagnosed as Lyme Disease in NJ," Presented by Centers for Disease Control & Prevention, David Dennis, at Congressman C. Smith's Lyme Forum, Wall Township, NJ, Oct. 1992
v[5] Department of Labor & Statistics CPI calculator
vi[6] *J Neuropsychiatry Clin Neurosci 2001*, Tager,F, Fallon BA, "Controlled Study of Cognitive Deficits in Children With Chronic Lyme Disease"
vii[7] *The Journal of Neuropsychiatry & Clinical Neurosciences*, 2013, Batheja S., "Post Treatment Lyme Syndrome & Central Sensitization"
viii[8] *BMJ* 2007; 335:1008, Stricker RB, Johnson L. "Lyme wars: let's tackle the testing."
ix[9] http://www.uspreventiveservicestaskforce.org/uspstf05/hiv/hivrs.htm

Patricia V. Smith Lyme Disease Association

MAJOR POINTS SUMMARY

1. Lyme disease is increasing in numbers and range worldwide, with CDC announcing U.S. cases are 300,000 annually. It is found in about 80 countries worldwide.
2. A government study has indicated the impact of Lyme disease on patients is as severe as disability of patients with congestive heart failure or osteoarthritis, is greater than those observed in type II diabetes or in recent myocardial infarction, and chronic pain contributing to impairment is similar to that reported by patients with osteoarthritis.
3. Other tick-borne diseases are being discovered with greater frequency and people are becoming co-infected with a number of diseases.
4. More ticks are spreading different diseases to humans.
5. My work with the Lyme Disease Association has put me in close contact with patients who are sick and have other family members with the disease, which is costly to them financially and also impacts education and family structure.
6. Children are at the highest risk of acquiring Lyme disease. They often miss long periods of school and experience cognitive difficulties, severe pain, and may attempt suicide related to their Lyme disease.
7. There is a need for HR 610 creating an advisory committee which will permit all stakeholder input, including treating physicians, patients, and advocates, to be presented to government agencies. Currently patients have no voice.
8. The Committee would ensure that all sides of the science would be factored into the decision making process.
9. Government agencies need to interact with other government agencies, each bringing different perspectives and priorities to the table.
10. Having diverse stakeholders at the table ensures all perspectives are heard to develop a comprehensive coordinated approach to tick-borne diseases, helping ensure that government funding is used widely.
11. Truth in science can be achieved through open discussion with diverse viewpoints in an independent process free from bias and conflicts of interest.

Mr. PITTS. The Chair now recognizes Ms. Crandall for 5 minutes for opening statement.

STATEMENT OF LAURA CRANDALL

Ms. CRANDALL. Good afternoon. Thank you. I am very grateful to have this opportunity to speak with you regarding the Sudden Unexpected Death Data Enhancement and Awareness Act. The problems that the bill seeks to address were first made known to me through a very personal experience. I recall July 30th, 1997 as a beautiful, beautiful gorgeous summer day as I sat out on our front steps waiting to awaken my daughter Maria from her nap. She had her 15-month checkup scheduled for later that morning, but I went to—when I went to wake her in her crib, I found Maria not breathing and blue. I called 911 on speaker phone, I started CPR, and even though the police arrived immediately and care was intervened immediately, she was transported to the hospital, heroic efforts. Maria could not be revived. A thriving, happy, walking, talking, beautiful little girl had died. We returned home from the hospital to find the police waiting for us with lots of questions and needing to investigate our home.

A medical investigator from the ME's office called and came over the next morning to take pictures and ask many more questions and asked me to replay the most horrific moment of my life, how I found my daughter. Over the next few days, it was all we could do to plan her funeral and try to keep ourselves going on. I had no idea that during those same days that the investigation of Maria's death was the most crucial. I did not know that what was and what was not done at that time would have such a lasting impact on myself and the rest of my family. It is not like TV. Nothing happens quickly, and questions don't get answered in an hour, if they ever do at all.

Two long years later, her investigation was concluded and a cause for her death was never found. So I am left with the understanding that her true cause of death was buried with her, and that is a tragedy of missed opportunities that I live with. I do not want to see this happen for other families in the future.

Sadly, my story is not unique. There are many bereaved families who could sit in this chair and tell you the same story of tragedy, inexplicable loss, and missed chances. In 2010 alone, over 3,600 infants and nearly 200 toddlers died suddenly and without explanation, and in over 26,000 babies were lost to stillbirth. H.R. 669 efficiently addresses the core problems present in our country today to allow us to improve the collection of comprehensive and standardized information to better understand these presently inexplicable deaths.

Regarding stillbirths. Nearly half of the 26,000 are unexplained. Its surveillance is very limited when utilizing fetal death records, which are often incomplete and insufficient. However, a CDC-funded effort to gather richer data through some existing State birth defects surveillance programs have shown success. Education of health care providers and expectant families is also limited and needed to teach the importance of known prenatal health initiatives.

In regards to infant and childhood deaths, coroner and medical examiner offices have the authority in our country to investigate all unexplained, unexpected, and suspicious deaths, and therefore, the infant and child deaths that we discussed today fall under their purview. In this regard, it is very important to recognize that the death investigation systems in our country vary immensely from State to State and often from county to county. Therefore, the investigations that parents encounter are directly tied to where they live and the resources and the policies which their local medical examiner or coroner officer utilizes.

The tracking of sudden unexpected infant death rates showed a significant drop in the early 1990s with the initiation of NICHD successful back-to-sleep campaign. Unfortunately, we have not seen any additional progress in lowering those rates further. As shown in the CDC graph I submitted in my written testimony on page 8, I believe, our progress as a country has seen a plateau for more than a decade, and if we are committed to see a change and prevent more of these deaths in the future, we must make a change in our process.

The medical legal death investigation of these cases needs to be standardized, they need to be resourced, and the resultant data centralized and specifically studied. The Sudden Unexpected Death Data Enhancement and Awareness Act addresses these critical limitations in order to provide answers to families as well as our Nation overall.

Specifically, it would improve the effectiveness of current activities of the CDC by removing the obstacles that impede their success today. This will be achieved by improving the surveillance of stillbirth by expanding on current programs, improving the surveillance of infant and child deaths by supporting comprehensive investigations, supporting evidence based public awareness campaigns and providing relief to families.

Thank you for allowing me to provide my views on this important legislation, and on behalf of all the children gone too soon, my Maria being one of very many, thank you forgiving them a voice. I know they would want us to know what happened to them and help create a future free of tragedies for others.

[The prepared statement of Ms. Crandall follows:]

Testimony for HR 669
November 20, 2013
Committee on Commerce: Sub-committee on Health

Laura Crandall
Program Director of The Sudden Unexplained Death in Childhood Program
a program of the CJ Foundation for SIDS

Summary Page

- In 2010 alone, over 3,600 infants and nearly 200 toddlers died suddenly and without explanation and over 26,000 babies were lost to Stillbirth.
- SUID rates first decreased in the 1990's during the "Back to Sleep" campaign but have since remained unchanged since the late 1990's.
- Greatest Need Today to Address: Inconsistent data collection of fetal, infant and childhood deaths limits our ability to fully inform parents and address these public health issues.
- The medicolegal death investigation of these cases needs to be standardized, resourced, and the resultant data centralized and specifically studied as supported in HR669.
- Specifically, HR669 will improve the effectiveness of the current activities of the CDC by recognizing and addressing the current obstacles their projects face by:
    - Ensuring comprehensive autopsies
    - Improving Scene investigations of infant/child deaths
    - Improving the Surveillance of Stillbirth
    - Improving the Surveillance of Infant/Child Deaths
    - Supporting Evidence Based Community Interventions
    - Supporting Evidence Based Public Awareness Campaigns
    - Supporting Bereaved Families

Oral Testimony

My Personal Story

Good afternoon. My name is Laura Crandall and I am grateful to have this opportunity to speak with you regarding HR669 - the Sudden Unexpected Death Data Enhancement and Awareness act. The problems that the bill seeks to address were first made known to me through a very personal experience.

July 30th 1997 was a gorgeous summer day- 80 degrees, sunny and completely blue skies- that is what I remember that morning sitting out on our front steps while waiting to awaken my daughter, Maria, from her nap. She had her 15 month pediatric well visit scheduled for later that morning. But when I went to wake her, I found Maria in her crib- not breathing and blue. I called 911, did CPR and even with the immediate efforts of Police, EMTs and those at the ER- Maria could not be revived. She had died- a thriving, happy, walking, talking beautiful little girl died.

We returned home from the hospital to find the police waiting for us with lots of questions and needing to investigate our home. A medical investigator from the ME's office called and came over the next morning to take pictures and ask many more questions, and asked me to replay the most horrific moment of my life- how I found Maria. Over the next few days, it was all we could do to plan her funeral and try to keep ourselves going on. I had no idea that during those same days, that the investigation of Maria's death was the most crucial. I did not know, that what **was,** and **was not** done at that time would have such a lasting impact on myself and the rest of my family.

It is not like TV- nothing happens quickly. Questions don't get answered in an hour- if they ever do at all. Two long years later, her investigation was concluded and- a cause for her death was never found. So I am left with the understanding that her true cause of death was buried with her, and

that is a tragedy of missed opportunities. I do not want to see this happen for other families in the future.

Sadly, my story is not unique. There are many bereaved families who could sit in this chair and tell you the same story of tragedy, inexplicable loss and missed chances. In 2010 alone, over 3,600 infants and nearly 200 toddlers died suddenly and without explanation and over 26,000 babies were lost to Stillbirth. HR669 efficiently addresses the core problems present in our country today to allow us to improve the collection of comprehensive and standardized information to better understand these presently inexplicable deaths.

Issues related to Stillbirth

Of the 26,000 babies a year in the U.S. who are stillborn, nearly half go unexplained. Additionally, deaths due to Stillbirth represent almost half of all our country's perinatal deaths. This is a significant public health issue and one who's current surveillance is quite limited through fetal death records with studies showing that the data collected is often incomplete and insufficient.

The state of Iowa, Metropolitan Atlanta and, more recently, counties around Denver, parts of Hawaii and Western NY have joined in a CDC funded effort to gather comprehensive and standardized data through their existing birth defect surveillance programs. This includes more qualitative data like pregnancy related and post mortem information. Studies have shown the benefit of such a program structure far outweighs the information gathered from the fetal death record system alone.

Education of healthcare providers and expectant families is also needed to emphasize and teach the importance and potential benefit of known prenatal health initiatives that is not standardized today.

Issues related to Infant and Childhood Deaths

One of the great barriers to understanding infant and child deaths is the recognition that death investigation systems in our country vary greatly. Coroner and medical examiner offices are charged and have the authority to conduct medicolegal death investigation of all unexplained, unexpected, and suspicious deaths in the United States. Consequently, all of the unexpected infant and child deaths we speak of today will/should undergo a medicolegal death investigation.

It is clear, however, that the medicolegal death investigation system in our nation is poorly-funded and without consistency and standardization from state to state, and often from county to county. The investigation that parents encounter, is directly tied to where they live and the resources and policies which their local Medical Examiner or Coroner's office utilizes. I also know, from working with the National Association of Medical Examiners, specifically Dr Victor Weedn, as well as the Scientific Working Group for Medicolegal Death Investigation, that the federal government has little influence on coroner and medical examiner systems with only the Armed Forces Medical Examiner System under its purview. Additionally, the only federal assistance that coroner and medical examiner offices receive is through the Paul Coverdell grants.

It is also clear that the investigations of unexpected infant or child deaths are some of the most difficult cases for the medicolegal death investigation system. They require a thorough investigation of the scene where the child was found, comprehensive interviews of the caregivers, a review of the child's medical history, and a "complete" autopsy. Guidelines for scene investigation created by the CDC are not universally adopted and there are no national guidelines or standards for what constitutes a complete autopsy of a sudden infant or child death. This results

not only in incomplete information for the family struggling to understand their loss, but drastically limits the ability of public health to address problem.

Currently, little medical headway has been made with regard to understanding the nature of unexpected and unexplained deaths of fetuses, infants, and young children, because they occur sporadically and because an overarching structure is not in place to study these cases, and thus the information about each case lays fallow. This is yet another source of long term distress to the family - that their child's death will not assist in the prevention of another.

The tracking of sudden unexpected infant death rates showed a significant drop in the early 1990's with the initiation of NICHD's successful "Back to Sleep" campaign- unfortunately, we have not seen any additional progress in lowering the rates further. As shown in the CDC graph I submitted in my written testimony (page 8), our progress as a country has seen a plateau for more than the last decade. If we are committed to **see** a change and prevent more of these deaths in the future, we must **make** a change in our process. The medicolegal death investigation of these cases needs to be standardized, resourced, and the resultant data centralized and specifically studied as described in HR669. The Sudden Unexpected Death Data Enhancement and Awareness Act addresses these critical limitations in order to provide answers to families and our nation overall.

Specifically, the bill will improve the effectiveness of the current activities of the CDC by addressing the current obstacles that impede their success by:

- Ensuring comprehensive autopsies: Creating and supporting national guidelines for the standardization of autopsies for infants and children who die unexpectedly.

- Improving Scene Investigations: Supporting the specialized infant/child death investigation training needed for death investigators.
- Improving the Surveillance of Infant/Child Deaths: Enhancing the national case reporting system to better track infant and childhood deaths and identify risk factors to prevent them in the future.
- Supporting Evidence Based Community Interventions: Expanding successful child death review programs to track and analyze the circumstances surrounding infant's and children's deaths in their community to create/implement evidence based initiatives to prevent them.
- Improving the Surveillance of Stillbirth: Expand current data collection activities to additional states to identify the causes of stillbirth and ways to prevent it in the future.
- Supporting Evidence Based Public Awareness Campaigns: Create a national public awareness and education campaign to educate parents and caregivers about known risk factors for stillbirth, and sudden unexpected death in infancy and childhood.
- Supporting Bereaved Families: Expand support services, such as grief counseling, for families who have experienced stillbirth, or sudden unexpected infant or child death.

Our country is in dire need of standardized protocols for death scene investigations and comprehensive autopsies. This will ensure that our public health and research efforts are driven by data that is complete and consistent. Each individual family expects and deserves this as well.

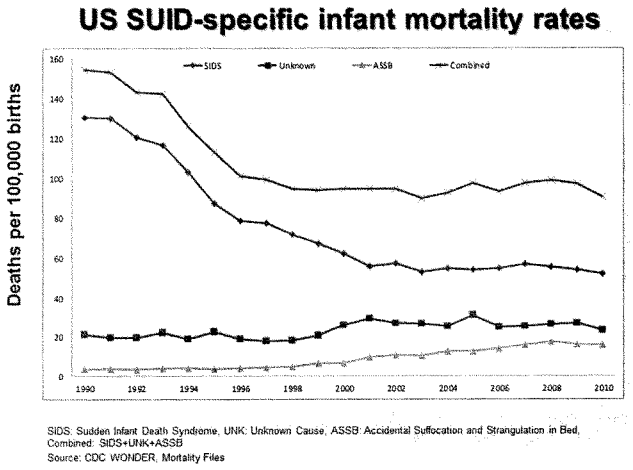
Thank you for allowing me to provide my views on this important legislation. And, on behalf of all the children gone to soon (my Maria, being one of so many) thank you for giving them a voice. I know they would want us to know what happened to them and help create a future free of these tragedies for others.

Additional Rationale for HR669

Statistics of Sudden Unexpected Infant and Toddler Deaths

The most recent rates of Sudden Unexpected Infants Deaths from 2010 are reported by the CDC include: 2,063 SIDS, 918 Undetermined, and 629 to ASSB for a total of 3,610 sudden unexpected infant deaths.

Rates of Sudden Unexplained Death in Childhood are estimated from deaths ruled Undetermined (as SUDC does not have a specific diagnosis code). In 2010, there were 198 undetermined deaths of children ages 1- 4 years.



Data from the CDC's tracking of death certificates from 1990 to 2010 shows an overall decrease in the total number of infants dying unexpectedly. This initial drop coincides with the initiation of the

"Back to Sleep" campaign initiated in 1994 by the NICHD. The lowest line (in green) for ASSB (accidental suffocation and strangulation in bed) shows a gradual increase in recognition of these preventable asphyxia related deaths and this uptrend correlates to the CDC's release and training of scene investigation guidelines for sudden unexpected infant death. While SIDS (in blue) and Undetermined (in red) may represent a shift in the way the deaths are being classified, it is more important to our discussions today that the overall rate of SUID (in purple) has seen a plateau in our country since the late 1990's. Therefore, the efforts we have pursued over the last 10 plus years have not materialized in continued progress to decrease the incidence of these deaths further.

The successful efforts of the National Institute of Child Health and Human Development (NICHD), in public awareness campaigns, and the CDC in scene investigative guidelines as well as tracking sudden infants deaths are apparent and have proven their success in the ultimate goal-the reduction of sudden infant death. However, we are here today discussing HR669 because of the stagnation in our further progress for more than a decade which causes us to look closely at our systems to remove the obstacles that may be contributing to this.

Investigating Sudden Infant and Child Deaths

Over the last twelve years, I have worked with hundreds of families after the loss of a child, as well as worked with many dedicated professionals from all across our country who deal directly with the aftermath of a sudden child death. These include Medical Examiners, Coroners, Death Investigators, Law Enforcement, Pediatricians, Child Death Review team volunteers, Public Health professionals and Researchers.

All perform specific roles that are critical to our understanding of sudden deaths whether they be investigative, clinical care of the family, public health goals, and/or research.

Their success is strongly dependent on the consistent and thorough case information primarily collected in a critical window of opportunity- within 24 hours of the death. Families in crisis and shock have no idea that those initial hours after their child's death will be the most critical to the investigation- which either provide them comfort in the years ahead that every attempt was made to understand their child's death **or** provides them with a lifetime of regret of missed opportunities and unanswerable questions.

Death investigation systems vary throughout our country and so too do the specific investigations that exist. Resources, training and experience vary. There is no standardization for autopsies that exist similar to the scene investigation guidelines created by the CDC. And the difficulty of investigating these sudden deaths takes several weeks or many months before a case report is completed.

Simultaneously, there is an investigation by law enforcement to determine if a crime has been committed, all the while, young families are grappling with their loss, planning funerals and explaining to siblings why their brother or sister is not coming home.

We know that the creation and revision of the CDC's Sudden Unexplained Infant Death Reporting Form (SUIDIRF) guidelines, training manual and curriculum coincide with improved data collection and have helped identify some causes of death that otherwise would have been left unexplained. However, the continued need for training is apparent. Death Investigators explain that these are some of the most difficult cases they work on. Not only are they extremely emotional and stressful environments but their investigation is heavily reliant on their ability to interview highly distraught parents and collect detailed and delicate information from them. Additionally, the scene is virtually always disturbed and chaotic due to rescue efforts at the home and frequent transportation to a hospital which results in them investigating the scene without the baby present

after some time. These advanced skills require specialized training, covered in the CDC's training curriculum for SUID, to collect important information that the pathologist needs before they perform the autopsy.

For more information: http://www.cdc.gov/sids/SUIDAbout.htm

Current efforts of the CDC regarding Sudden Unexplained Infant Deaths (SUID)

In addition to the CDC's SUIDIRF, the SUID case registry project was created in 2010 by the CDC in partnership with the National Center for Child Death Review (NCCDR), and is funded by the Health Resources and Services Administration. Currently it includes 9 pilot states (Arizona, Colorado, Louisiana, Michigan, Minnesota, New Jersey, New Mexico, New Hampshire, and Wisconsin) who partner to collect and analyze comprehensive information on sudden infant deaths that occur in their state. Data is analyzed after the investigation is complete through the child death review process and utilized to create prevention strategies and enter the data into the web-based reporting system of NCCDR.

For more information: http://www.cdc.gov/sids/CaseRegistry.htm

The SUID case registry does not support or impact the training of death investigators, nor address the lack of standardization and quality of autopsies and therefore the data that is collected is often incomplete and weakens the strength of its analysis.

Current efforts of CDC regarding Sudden Unexplained Deaths in Childhood (SUDC)

There are no current efforts by the CDC to address SUDC specifically. Sudden Unexplained Death In Childhood of 1- 4 year olds is more rare that Sudden infant death. SIDS being 40 times more common than SUDC. Not surprisingly, there is little known about these deaths and due to their rarity, they are very difficult to study by any one jurisdiction, state or even region. There are also

no scene investigative standards or autopsy guidelines for these deaths. Therefore the collection of comprehensive data on SUDC cases is extremely limited but its collection is vital to improving our understanding and pursuit of its prevention.

Investigating Stillbirth and Current Efforts of the CDC

Approximately 26,000 babies a year in the US are stillborn (using the definition of 20 weeks gestation or more) which represent nearly half of all perinatal deaths. Additionally, there is not an identifiable causes for about half of all Stillbirths.

Current surveillance of Stillbirths occurs most commonly through fetal death records but studies show that the data collected is often incomplete and insufficient. (see references)

Post mortem investigations (autopsies) are also limited in Stillbirth, estimated as less than 40%. Postmortem findings often take weeks to finalize and therefore are often not included in fetal death records which are submitted within days of death. Although guidelines for Stillbirth investigation have been created by ACOG, it is clear they are not widely used.

The state of Iowa, Metropolitan Atlanta and, more recently, counties around Denver, parts of Hawaii and Western NY have joined in a CDC funded effort to gather comprehensive and standardized data through their birth defect surveillance program on Stillbirth which includes pregnancy related data and post mortem information. Studies have shown the benefit of such a program structure outweighs the information gathered from the fetal death record system alone.

Education of healthcare providers and expectant families is also needed to emphasize and teach the importance and potential benefit of prenatal health initiatives such as fetal movement awareness, G group B strep screening, obesity prevention/treatment, etc.

HR669 seeks to address Stillbirth by expanding state-based registries and standardized surveillance data to 8-9 states in order to provide a representative sample of Stillbirth deaths in the U.S. which will aid public health in creating evidence based strategic initiatives and fostering meaningful research to better understand the thousands of Stillbirths that occur each year each year.

The Greatest Need Today: Improve Data Collection!!!

The lack of progress seen in the CDC SUID rates since the late 90's forces us to examine the complicated process when an infant or young child dies. This includes the medicolegal death investigation system as well as the efforts of those trying to understand and prevent these deaths through public health and research.

HR669 strategically addresses the single most important factor that effects our ability to inform families, arm public health with comprehensive and standardized information they can rely on to determine risk factors and create evidence based intervention measures, as well as, foster successful research by being able to ensure accurate and consistent data.

HR669 will improve the collection and analysis of standardized data that is only available in the first crucial hours of the investigation- and prevent it from being lost forever- and thereby maximize the ability to learn from every one of these tragic death.

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Mr. PITTS. Thank you. Thank you very much for your testimony. Mr. MtJoy, you are recognized for 5 minutes for your opening statement.

STATEMENT OF ROBERT MTJOY

Mr. MTJOY. Chairman Pitts, Ranking Member Pallone, and distinguished members of the——

Mr. PITTS. Pull your mike a little closer if you could, yes.

Mr. MTJOY. My name is Robert MtJoy, and I am chief executive officer——

Mr. PITTS. Is it on? Is the red light on?

Mr. MTJOY. It is on now.

Mr. PITTS. OK. Good.

Mr. MTJOY. My name is Robert MtJoy. I am chief executive officer of Cornerstone Care. On behalf of the 23,000 patients that we serve, our 186 employees, the entire health center community, including more than 22 million patients nationwide served by health centers, I want to thank you for this opportunity to testify today regarding the Family Health Care Accessibility Act of 2013 and for this subcommittee's strong support of health centers for many years.

In particular, I want to thank Congressman Murphy for introducing this important legislation that would benefit health centers and their patients across the country by extending the Federal Tort Claims Act medical malpractice coverage to licensed health care professionals who volunteer their services at health centers.

Health centers are community-owned, nonprofit entities providing primary medical, dental, and behavioral health care. By statute and mission, health centers are located in medically underserved areas or serve medically underserved populations. Health centers are also directed by patient-majority boards, ensuring care is locally controlled and responsive to each individual community's needs. Health centers provide primary care to all residents of their communities, regardless of their ability to pay or insurance status and offer services on a sliding fee scale.

To date, there are over 1,200 health centers located across the Nation at more than 9,000 urban and rural health locations. Without their local health center, these communities and patients would often be without any access to primary care. Health centers have a demonstrated track record of improving the health and wellbeing of their patients, while at the same time, reducing unnecessary avoidable and wasteful use of health resources. Health centers reduce preventable hospitalizations, emergency department use, as well as the need for more expensive specialty care.

Cornerstone Care was formed as a direct result of citizens who organized a board of directors and raised funds in 1978 to provide health care where before none had existed. The first doctors joined the organization in 1981. Dental care, soon after, in a small church building in a neighboring community. Thirty-five years later, Cornerstone Care provides a full range of primary and preventive health care services in Greene, Washington, and Fayette counties in southwestern Pennsylvania through its eight facilities, a mobile unit, and a teaching health center.

Regarding the bill of interest to the committee today, by way of background, in 1993, Congress extended the Federal Tort Claims Act coverage to health center grantees by deeming them Federal employees for the purposes of medical malpractice coverage. The extension of the FTCA to health centers have resulted in significant savings for health centers, savings that have been used to expand access to care for millions of patients.

There are health care professionals who want to assist health centers in serving their communities and addressing this unmet need by volunteering their services. However, the high cost of medical liability insurance often provides to be too burdensome for the provider and the health center, preventing these volunteers from doing so.

While health centers are engaged in many workforce development initiatives, one immediate solution to alleviate this workforce shortage is the use of volunteer providers. By extending FTCA coverage to include volunteer providers, there will be more providers available to meet the needs of millions of patients who still lack care.

Recruitment and retention of health care providers is one of the greatest challenges I have. And unfortunately, the looming critical shortage of primary care physicians will be more profoundly felt in rural areas like mine. We have got an aging physician population getting ready to retire, and this bill allows us to take advantage of this valuable resource.

Mr. Chairman, there is significant unmet needs in our communities that health centers could address. The Family Health Care Accessibility Act is vital to the effort of addressing the Nation's primary care shortage. I would be remiss if I also forgot to mention two other vital programs that support the goal of creating medical homes for underserved Americans: The National Service Corps and the Teaching Health Centers Graduate Medical Education Program. These programs play important roles in addressing primary care workforce shortages and most—and both must be authorized soon if they are to continue.

We look forward to working with you and other members of this subcommittee to improve access to primary care and reduce the overall health care costs in our community and across the country.

[The prepared statement of Mr. MtJoy follows:]

Mr. Robert MtJoy
Chief Executive Officer
Cornerstone Care, Inc.
Testimony to the House Energy and Commerce Subcommittee on Health
"Examining Public Health Legislation to Help Local Communities"
November 20th, 2013

Chairman Pitts, Ranking Member Pallone, and Distinguished Members of the Subcommittee:

My name is Robert MtJoy, and I am the Chief Executive Officer of Cornerstone Care, Inc. in Pennsylvania. On behalf of the 23,000 patients that we serve at Cornerstone Care, our 186 employees and the entire health center community, including more than 22 million patients nationwide served by health centers, I want to thank you for the opportunity to testify today regarding the Family Health Care Accessibility Act of 2013 and for this Subcommittee's strong support of health centers for many years. In particular I want to thank Congressman Tim Murphy for introducing this important legislation which would benefit health centers and their patients across the country by extending Federal Tort Claims Act (FTCA) medical malpractice coverage to licensed health care professionals who volunteer their services at Health Centers.

Health centers are community-owned non-profit entities providing primary medical, dental, and behavioral health care. In addition, many health centers also provide pharmacy and a variety of enabling and support services. By statute and mission, health centers are located in medically underserved areas or serve a medically underserved population. Health centers are also directed by patient -majority boards, ensuring care is locally-controlled and responsive to each individual community's needs. Health centers provide comprehensive primary care to all residents of their communities, regardless of ability to pay or insurance status and offer services on a sliding fee scale. To date, there are over 1,200 health centers located at more than 9,000 urban and rural locations nationwide serving as medical homes for more than 22 million patients.

Without their local health center, these communities and patients would often be without any access to primary care. Health centers have a demonstrated track record of improving the health and well-being of their patients using a locally-tailored health care home model designed to coordinate care and manage chronic disease, at the same time reducing unnecessary, avoidable and wasteful use of health resources. Health centers reduce preventable hospitalizations and Emergency Department (ED) use, as well as the need for more expensive specialty care. Studies show that the services provided at health centers save $1,200 per patient per year compared to expenditures for non-health center users.

Cornerstone Care's first patient registered for an examination with a nurse practitioner in the former dining room of a two-story nineteenth century brick house on the banks of the Monongahela River in Greensboro, Pennsylvania. This was the direct result of a group of citizens who organized a board of directors and raised funds in 1978 to provide health care where before none had existed. The first doctors joined the organization in 1981. Dental Care began soon after in a small church building in a neighboring community.

Thirty Five years later, Cornerstone Care provides a full-range of primary and preventative health care services in Greene, Washington, and Fayette Counties in SW Pennsylvania through its eight modern facilities, one mobile unit, and a teaching health center. Statewide, community health centers provide quality primary medical, dental and behavior care to over 700,000 patients annually in over 250 rural and urban medically underserved locations.

Regarding the bill of interest to the Committee today, by way of background, in 1993, Congress extended FTCA coverage to health center grantees along with their officers, directors, employees and certain contractors by deeming them Federal employees for the purposes of medical

malpractice coverage. This was done to ensure federal health center grant funds were going to patient care and were not being eroded by the cost of private malpractice insurance coverage. Prior to this coverage, health centers purchased private malpractice insurance to cover their medical and professional staff. The Health Resources and Services Administration (HRSA) estimates that the extension of FTCA to health centers has resulted in significant savings for health centers – savings that have been used to expand access to care for millions of patients.

Demand for health center services continues to increase and surpass current provider capacity. There is a measurable shortage of health care providers in the communities served by health centers and recruitment and retention of health professional staff continues to pose a challenge. There are many health care professionals who want to assist health centers in serving their communities and addressing this unmet need by volunteering their services, however, the risk of liability and the high cost of supplemental medical liability insurance often prove to be too burdensome for the provider and the health center, preventing these volunteers from doing so.

Access to affordable primary care continues to pose one of the most persistent challenges in our health care system. Research indicates that approximately 60 million Americans live in a community without access to a primary care provider. While health centers are engaged in many workforce development initiatives, one immediate solution to alleviate this workforce shortage is the use of volunteer providers. According to a 2009 Government Accountability Office (GAO) report on the implications of extending FTCA coverage to health center volunteers, only 7 percent of health centers reported using volunteers. By extending FTCA coverage to include volunteer providers, there will be more providers available to meet the needs of the millions of patients who still lack access to care.

Recruitment and retention of health care provider is one of the greatest challenges I have. And unfortunately the looming critical shortage of primary care physicians will be more profoundly felt in rural areas like mine. We've got an aging physician population getting ready to retire and this bill allows us to take advantage of this valuable resource to assist us in addressing this shortage.

In the aforementioned 2009 GAO report, the Congressional Budget Office (CBO) estimated that the cost of this expansion would be negligible: $6 million over five years. More recent CBO estimates indicate that this expansion could cost approximately $30 million over five years. Because the health center FTCA judgment fund is appropriated as a subpart of annual Health Center program appropriations, however, this law could be implemented without the addition of a new annual appropriation line item.

Mr. Chairman, there is significant unmet need in our communities that health centers could address. We stand ready to meet the demand among those in need of primary care. However, health centers can only meet these primary care demands if we can provide access to the appropriate providers. The Family Health Care Accessibility Act is vital to the effort of addressing this nation's primary care shortage.

I would be remiss if I failed to mention two other vital programs that support the goal of creating medical homes for underserved Americans: the National Health Service Corps (NHSC) and the Teaching Health Centers Graduate Medical Education program. These programs play important roles in addressing primary care provider workforce shortages and both must be reauthorized soon if they are to continue.

We look forward to working with you and the other members of this Subcommittee to improve access to primary care and reduce overall health care costs in our community and across the country.

Thank you, Mr. Chairman.

Mr. Robert MtJoy
Chief Executive Officer
Cornerstone Care, Inc.
Testimony to the House Energy and Commerce Subcommittee on Health
"Examining Public Health Legislation to Help Local Communities"
November 20th, 2013

- Health centers are community-owned non-profit entities providing primary medical, dental, behavioral health care, pharmacy and a variety of enabling and support services for 22 million patients nationwide. Cornerstone Care provides these services for XX patients in Pennsylvania.

- Health centers are located in medically underserved areas or serve a medically underserved population providing comprehensive primary care to all residents of their communities, regardless of ability to pay or insurance status and offer services on a sliding fee scale. Without their local health center, these communities and patients would often be without any access to primary care

- In 1993, Congress extended Federal Tort Claims Act coverage to health center grantees along with their officers, directors, employees and certain contractors to ensure federal health center grant funds were going to patient care and not to offsetting the cost of private malpractice insurance coverage.

- The extension of FTCA to health centers has resulted in significant savings for health centers that have been used to expand access to care for millions of patients, but the demand for care at health centers continues to outpace provider capacity. This is further compounded by the challenges of recruiting and retaining providers in communities served by health centers.

- One way to increase the number of providers at health centers is to tap into the numerous licensed health care practitioners who wish to volunteer at health centers. However, risk of liability and the high cost of supplemental medical liability insurance often prove to be too burdensome for the provider and the health center, preventing these volunteers from actually volunteering.

- Rep. Tim Murphy and Rep. Gene Green's legislation, the Family Health Care Accessibility Act of 2013, would extend FTCA coverage to include licensed volunteer providers at health centers. This legislation would increase the number of primary care providers at health centers to meet the needs of the millions of patients who still lack access to care at a minimal cost to the federal government.

Mr. PITTS. The Chair thanks the gentleman. That concludes the opening summaries of our witnesses. We will now begin questioning by the members. I will recognize myself 5 minutes for that purpose.

Dr. Nagele, since you are from Pennsylvania, can you describe for us how the Federal TBI State Grant Program impacted the State of Pennsylvania and its TBI population?

Mr. NAGELE. Yes. In Pennsylvania, we have had a HRSA grant for many years now, and one of the functions that we have used it for is training and education. We have trained many different types of people on what brain injury is and how to help people with brain injury to access brain injury services which are available. We had started training mental health workers and prison personnel, and the work that we did with the prison personnel have actually led us to another grant opportunity with the Pennsylvania Commission on Crime and Delinquency, and so the initial TBI Act funds helped us to leverage and get another grant where we are actually in the prisons now doing screening of inmates who are about to be released, and for those who are determined to have a brain injury, which is about 70 percent in our early——

Mr. PITTS. 70 percent?

Mr. NAGELE. 7–0 percent, yes.

Mr. PITTS. What is the predominant reason for all the brain injuries?

Mr. NAGELE. Mostof them are mild repeated brain injuries that have never been diagnosed. So these inmates are not thinking of themselves as having had a brain injury. They are just thinking they got in a fight or they were in a car wreck or they were in a fall. They were never treated for these injuries, and as we are learning from the NFL studies, repeated mild brain injury can lead to much more serious problems in later life, and so these prisoners have had brain injury, but it has never been diagnosed, and our current work is to connect them with brain injury services when they leave the prisons so that they have every chance of success in the community and they don't end up back in prison.

Mr. PITTS. Thank you.

Ms. Crandall, I found your testimony very moving. H.R. 669 calls for the improvement of death scene investigations in the case of sudden unexplained death in childhood, including the collection of medical information, description of the sleep position, environmental factors. Would collecting this information significantly lengthen the time it takes to complete the current investigation?

Ms. CRANDALL. No. And the guidelines currently exist for scene investigation through the CDC, were first created in the mid 1990s and then revised in 2005, I believe. Those guidelines are out there, but they are not universally utilized for infants, and that information is very helpful to the pathologist prior to them performing the autopsy, so they know what may be a concern and whatnot. So those guidelines are out there right now. Those are ideally captured within, on the day of the death, when the death investigator goes to the place where the infant or child died and interviews the caregivers and collects that important data. So, it would not increase the length of time.

Mr. PITTS. Do you know if local police or other law enforcement authority support these changes?

Ms. CRANDALL. I believe in the last legislative session, I know that the—there was a National Sheriffs Association, I believe, that endorsed the bill. In general, again, death investigations vary so greatly. In some areas, local law enforcement are the deathinvestigators, and in other areas, they are medical legal death investigators from the medical examiner's office or coroner's office doing an investigation in parallel, so it varies from jurisdiction to jurisdiction on how these would be carried out, but the information from law enforcement is very helpful to them in terms of giving them a guidebook of what to follow.

As you can imagine, these are emotionally and very chaotic scenes. It is very difficult. It is some of the most difficult investigations that death investigators say they need to respond to as well as law enforcement because the scene is completely disturbed by the time they get there. So, their ability to effectively interview a distraught parent, to get that accurate information of what really happened really takes an important skill set, and that is why the training for these death investigators is so important. It is really a unique highly skilled ability that they need to have to be able to collect this information and do it in the most compassionate way for the families.

Mr. PITTS. Thank you.

Ms. Smith, one of our colleagues, who does not serve on the Energy and Commerce Committee, Chris Gibson from New York's 19th District, has been a tireless advocate for his constituents on the issue of Lyme disease, and he has submitted a question that he would like me to ask on his behalf.

Ms. Smith, you mentioned the concentration of existing research dollars and the lack of diversity and coordination in Lyme research, and this was a helpful analysis. Can you identify any areas of progress first, and what has worked and been helpful and what has not?

Ms. SMITH. I am sorry. I have a little bit of hearing impairment. Could you just repeat the last portion of that question?

Mr. PITTS. Yes. What has worked and has been helpful and what has not worked or been helpful?

Ms. SMITH. I am sorry, in regards to?

Mr. PITTS. As far as areas of progress——

Ms. SMITH. Oh, OK. I am sorry.

Mr. PITTS [continuing]. In your analysis.

Ms. SMITH. OK. So as far as areas of progress, I think what has been helpful is in recent times that I think there has been more agency interest and more agency coordination in focusing on the amount of disease across the country. And so I think that because of that, the amount and the diversity of the disease, I mentioned the number of tick-borne diseases that are being transmitted, and so on and so forth, I think that that has all come into play to begin to focus research, not just on Lyme disease, but on other tick-borne diseases. How do patients react if they have more than one disease? You know, how are they able to diagnose? Because many of them don't have tests to diagnose, unfortunately, with, they don't have particular treatments for certain viral diseases.

And so I think the fact that now that the information is being more freely shared about these tick-borne diseases and it is coming in from a lot of university studies that are being done, not just in the United States, but throughout the world, I think that has been extremely useful.

Mr. PITTS. Thank you. My time has expired. I am sorry to go over.

Mr. Pallone, you are recognized 5 minutes for questions.

Mr. PALLONE. Mr. Chairman, I wanted to submit for the record endorsement letters from 24 organizations. This is with regard to the H.R. 669.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

List of Organizations that Endorse H.R. 669

CJ Foundation for SIDS

National Association of Medical Examiners

Sudden Unexplained Death in Childhood Program

First Candle

Juvenile Products Manufacturers Association

Kids In Danger

Cribs for Kids

International Association of Coroners and Medical Examiners

The Star Legacy Foundation

Maternity Care Coalition

Child Death, Near Death and Stillbirth Commission (of DE)

Safe Kids Upstate (SC)

Children's Hospital Association

Child Injury Prevention Alliance

Safe Kids Worldwide

Safe States

American Professional Society on the Abuse of Children

American Academy of Pediatrics

American Association of Nurse Practitioners

Association of State and Territorial Health Officials (ASTHO)

Association of Maternal and Child Health Programs (AMCHP)

Society for Advancement of Violence and Injury Research

Charlie's Kids Foundation

Society of Medicolegal Death investigators

CJ FOUNDATION for SIDS
LIVE CARE GROW

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March 1, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from The CJ Foundation for SIDS of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Regards,

Susan Hollander

Thank you for all your support!

Susan Hollander
President/Executive Director

The National Association of Medical Examiners®

31479 Arrow Lane, Marceline, MO 64658
660-734-1891 Fax: 888-370-4839 Email: name@thename.org Website: www.thename.org

February 28, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from the National Association of Medical Examiners of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669. The National Association of Medical Examiners (NAME) is the national professional organization of physician medical examiners, medical death investigators and death investigation system administrators who perform the official duties of the medicolegal investigation of deaths. It was founded in 1966 and has members in the United States and internationally.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

As medical examiners, we find preventable infant and childhood deaths among the most tragic and distressing of any deaths we investigate. Anything Congress can do to prevent them is most appreciated.

Gregory A. Schmunk, M.D.
President
National Association of Medical Examiners

Lindsey C. Thomas, MD

Lindsey C. Thomas, M.D.
Chair, Government Affairs Committee
National Association of Medical Examiners

SUDC
PROGRAM

February 28, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Re: Sudden Unexpected Death Data Expansion and Awareness Act
S.314/H.R.669

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from The SUDC Program of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Very truly yours,

Laura

Laura Crandall
Program Director & SUDC Parent

The SUDC Program c/o The CJ Foundation For SIDS
The Imus-WFAN Pediatric Center, 30 Prospect Avenue, Hackensack, NJ 07601

Tel: (800) 620-SUDC Fax: (973) 559-6191 E-mail: info@sudc.org Web: www.sudc.org

FirstCandle

March 8, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Representative Pallone:

Please accept this letter as a formal endorsement from First Candle of the *Sudden Unexpected Death Data Enhancement and Awareness Act* S314/HR669.

We applaud your vision to craft this bill. *The Sudden Unexpected Death Data Enhancement and Awareness Act* will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

As a national organization that has spent the past two decades working with thousands of families who have lost babies suddenly and unexpectedly, we understand the magnitude of these losses...for both individual families and for society. We commend your vision and applaud the timing of this important bill. Now, more than ever, surveillance, standardized protocols and education regarding Safe Sleep can continue to reduce the risk.

First Candle also applauds the inclusion of stillbirth awareness, education and prevention in the bill. With 70 stillbirths each day in our country we face a "silent epidemic". In years past many of these infants were too small to survive if they were delivered early. But now we have opportunity to change those outcomes through careful risk assessment and a better understanding of where and why so many these babies experience last trimester problems.

First Candle is available to assist you as the bills progress through Congressional committees. On behalf of our Board of Directors, as well as many parents, we truly thank you.

Most sincerely,

Kelly Mariotti

Kelly Neal Mariotti, CEO
1314 Bedford Avenue
Baltimore, MD 21208
kelly@firstcandle.org
Cell phone: 904-608-5613

November 20, 2013

JPMA

The Honorable Frank Pallone, Jr.
237 Cannon HOB
Washington, DC 20510

Dear Representative Pallone:

Please accept this letter as formal support from the Juvenile Products Manufacturers Association (JPMA) of the Sudden Unexpected Death Data Expansion and Awareness Act (S314, HR669).

The JPMA supports HR669 because the new research and education included in the bill would help reduce the number of unexpected infant deaths in America. Specifically, this bill would improve the collection of critical data to determine the causes of theses tragic deaths, increase education and awareness about how to prevent these tragedies in the future and expand support services for families who have experienced a stillbirth or SUID loss.

This bill is important to me because of our organization's commitment to our youngest and most vulnerable citizens. JPMA is a nonprofit association made up of children's products manufacturers who are dedicated to promoting the industry and the safe use of juvenile products.

Thank you for introducing this important piece of legislation. By working together, we will be one step closer to a future where all babies survive and thrive.

Warm regards,

Michael R. Dwyer, CAE
Executive Director
E-mail: mdwyer@jpma.org

KID IMPROVING CHILDREN'S PRODUCT SAFETY

116 W. Illinois
Suite 4E
Chicago IL 60654
Phone: 312.595.0649
Fax: 312.595.0939
www.KidsInDanger.org

March 6, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Representative Pallone,

Please accept this letter as a formal endorsement from Kids In Danger of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act would improve the collection of critical data to determine the causes of stillbirth and Sudden Unexpected Infant Death (SUID), increase education and awareness about how to prevent these tragedies in the future, and expand support services for families who have experienced a stillbirth or SUID loss. Too often information about unsafe products is missed because data collected is not comprehensive enough.

Sincerely,

Nancy A. Cowles

Nancy A. Cowles
Executive Director

Cribs for Kids®
Helping every baby sleep safer

March 14, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from Cribs for Kids, Inc. of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Sincerely,

Judith A. Bannon,
Executive Director/Founder

JAB/st

International Association of Coroners & Medical Examiners
Professionalism & Prevention
Dedicated to the promotion of excellence in medicolegal death investigation through annual educational seminars for over 70 years

March 14, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from The International Association of Coroners & Medical Examiners (IAC&ME) of the Sudden Unexpected Death Data Expansion and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Respectfully,

John Fudenberg
President Elect/Secretary
1704 Pinto Lane
Las Vegas, NV 89106
John.Fudenberg@theiacme.com

Star Legacy Foundation

Dedicated to Stillbirth Research and Education

Our Mission

Our mission is to increase awareness, support research, provide education regarding stillbirth.

Our Vision

There is great hope for the future to prevent many stillbirths in the United States and around the world. We intend to bring this hope to light. We are hopeful that through the utilization of technology, education and grassroots efforts, we can empower parents and families to be advocates for their unborn babies.

Contact Information

11305 Hawk High Court
Eden Prairie, MN 55347
952-715-7731
Fax: 866-305-9313
info@starlegacyfoundation.org
www.starlegacyfoundation.org

March 20, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from the Star Legacy Foundation of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Warmest Regards,

Lindsey J. Wimmer

Lindsey Wimmer, MSN, CPNP

Executive Director

Celebrate. Strengthen. Inspire.

April 12, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from (insert your organization's name) of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Sincerely,

Mary Texidor

Mary Texidor
Cribs for Kids Program Manager
Maternity Care Coalition
2000 Hamilton St, Ste 205
Philadelphia, PA 19130
(215) 989-3555
mtexidor@maternitycarecoalition.org

STATE OF DELAWARE
Child Death, Near Death and Stillbirth Commission
900 King Street, Suite 220
Wilmington, DE 19801-3341

April 23, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from the State of Delaware Child Death, Near Death and Stillbirth Commission of the Sudden Unexpected Death Data Expansion and Awareness Act s314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Expansion and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Respectfully submitted,

Marjorie L. Hershberger, MS, RN-BC, PNP-BC, CPNP
Specialist for Infant Safe Sleeping & SIDS
Commissioner Child Death, Near Death and Stillbirth Commission

Safe Kids
Upstate

August 2, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Safe Kids Upstate/Upstate Cribs for Kids is writing this letter as a formal endorsement of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We appreciate your vision in crafting this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the compilation of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced loss due to Stillbirth, Sudden Unexpected Infant Death (SUID) or Sudden Unexplained Death in Childhood (SUDC).

Sincerely,

Cynthia D. Fryer, MA
Manager, Children's Advocacy
Safe Kids Upstate
255 Enterprise Blvd., Ste. 110
Greenville, SC 29615

CHILDREN'S HOSPITAL ASSOCIATION

Champions for Children's Health

401 Wythe Street
Alexandria, VA 22314
p 703-684-1355
f 703-684-1589

6803 West 64th Street
Overland Park, KS 66202
p 913-262-1436
f 913-262-1575

September 10, 2013

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Robert Menendez
United States Senate
528 Hart Senate Building
Washington, DC 20510

Dear Senator Menendez and Representative Pallone:

We write to thank you for sponsoring the Sudden Unexpected Death Data Enhancement and Awareness Act, and to express our strong support for it. The bill's original sponsor in the Senate, Frank Lautenberg, who recently passed away, was a champion for child safety throughout his career. Passing this legislation would significantly improve infant safety and would be a fitting tribute to his legacy. We are ready to join you in moving it forward in both chambers.

What we know from the statistics reported by the Centers for Disease Control and Prevention ("CDC") – and especially what we do not know – tells the story of why this legislation is so critical. There are more than 4,500 Sudden Unexpected Infant Deaths ("SUIDs") in the United States each year, and half of these deaths are due to Sudden Infant Death Syndrome ("SIDS"). While it is suspected that 80-90 percent of the remaining deaths may be the result of unsafe sleep practices, we do not know for sure. The American Academy of Pediatrics recommends evidence-based safe sleep practices that include emphasizing: placing infants on their backs for sleep; using firm sleep surfaces in cribs with no soft objects or loose bedding; providing a smoke-free environment and room-sharing without bed-sharing. In order to further develop these and other safe sleep guidelines and to continue improving public education efforts around this topic, it is essential to have high-quality data on this important issue.

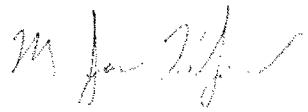
The CDC is trying its best to bring more consistency to information regarding SUIDs but is limited by diminished resources. We deeply appreciate the need for these data to develop the most practical and effective remedies, as do the CDC and pediatric institutions. This bill provides needed investments that will significantly improve the gathering and assessment of data regarding the circumstances surrounding SUIDs. This information is essential to identifying current risk factors contributing to SUIDs and tailoring public health efforts accordingly.

The public education and awareness role of the bill is also critical, because we know that public education can help reduce SUIDs. In 1994, the Back to Sleep public education campaign was launched by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"), now known as the Safe to Sleep campaign. This campaign has contributed to a significant decline in in SIDS deaths, but there is still an ongoing need for further progress that this bill's public education components would support. Finally, because there is nothing as tragic as parents having to plan a funeral for their baby, the expansion of support services, such as grief counseling, for families who have experienced a stillbirth or SUID loss is equally important.

Previously, this year, we joined with the following organizations in supporting this legislation: Safe Kids Worldwide, American Academy of Pediatrics, Child Prevention Injury Alliance, Safe States, ASTHO, American Association of Nurse Practitioners and First Candle.

Once again, we strongly support the passage of H.R. 669 on its merits and as a tribute to the career of the late Senator Frank Lautenberg. We look forward to working with your office to move this legislation forward. Thank you for your continued leadership in protecting our children.

Sincerely,



Jim Kaufman
Vice President, Public Policy
Children's Hospital Association

Child Injury Prevention Alliance
PO Box 30545
Columbus, OH 43230-7019

(614) 398-CIPA (2472)
www.childinjurypreventionalliance.org

Joint Letter in Support of H.R. 669

June 26, 2013

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Robert Menendez
United States Senate
528 Hart Senate Building
Washington, DC 20510

Dear Senator Menendez and Representative Pallone:

We write to thank you for sponsoring the Sudden Unexpected Death Data Enhancement and Awareness Act, and to express our strong support for it. The bill's original sponsor in the Senate, Frank Lautenberg, who recently passed away, was a champion for child safety throughout his career. Passing this legislation would significantly improve infant safety and would be a fitting tribute to his legacy. We are ready to join you in moving it forward in both chambers.

What we know from the statistics reported by the Centers for Disease Control and Prevention ("CDC") – and especially what we do not know – tells the story of why this legislation is so critical. There are more than 4,500 Sudden Unexpected Infant Deaths ("SUIDs") in the United States each year, and half of these deaths are due to Sudden Infant Death Syndrome ("SIDS"). While it is suspected that 80-90 percent of the remaining deaths may be the result of unsafe sleep practices, we do not know for sure. The American Academy of Pediatrics recommends evidence-based safe sleep practices that include emphasizing: placing infants on their backs for sleep; using firm sleep surfaces in cribs with no soft objects or loose bedding; providing a smoke-free environment and room-sharing without bed-sharing. In order to further develop these and other safe sleep guidelines and to continue improving public education efforts around this topic, it is essential to have high-quality data on this important issue.

The CDC is trying its best to bring more consistency to information regarding SUIDs but is limited by diminished resources. We deeply appreciate the need for these data to develop the most practical and effective remedies, as do the CDC and pediatric institutions. This bill provides needed investments that will significantly improve the gathering and assessment of data regarding the circumstances surrounding SUIDs. This information is essential to identifying current risk factors contributing to SUIDs and tailoring public health efforts accordingly.

The public education and awareness role of the bill is also critical, because we know that public education can help reduce SUIDs. In 1994, the Back to Sleep public education campaign was launched by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"), now known as the Safe to Sleep campaign. This campaign has contributed to a significant decline in in SIDS deaths, but there is still an ongoing need for further progress that this bill's public education components would support. Finally, because there is nothing as tragic as parents having to plan a funeral for their baby, the expansion of support services, such as grief counseling, for families who have experienced a stillbirth or SUID loss is equally important.

Child Injury Prevention Alliance
PO Box 30545
Columbus, OH 43230-7019

(614) 398-CIPA (2472)
www.childinjurypreventionalliance.org

Previously, this year, we joined with the following organizations in supporting this legislation: Safe Kids Worldwide, American Academy of Pediatrics, Safe States, Children's Hospital Association, ASTHO, American Association of Nurse Practitioners and First Candle.

Once again, we strongly support the passage of H.R. 669 on its merits and as a tribute to the career of the late Senator Frank Lautenberg. We look forward to working with your office to move this legislation forward. Thank you for your continued leadership in protecting our children.

Sincerely,

Dr Gary A. Smith
President
Child Injury Prevention Alliance

SAFE KIDS WORLDWIDE

1301 Pennsylvania Avenue, NW
Suite 1000
Washington, D.C. 20004

Kate Carr
President and CEO
kcarr@safekids.org | 202.662.0616

September 11, 2013

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Robert Menendez
United States Senate
528 Hart Senate Building
Washington, DC 20510

Dear Senator Menendez and Representative Pallone:

We write to thank you for sponsoring the Sudden Unexpected Death Data Enhancement and Awareness Act, and to express our strong support for it. The bill's original sponsor in the Senate, Frank Lautenberg, who recently passed away, was a champion for child safety throughout his career. Passing this legislation would significantly improve infant safety and would be a fitting tribute to his legacy. We are ready to join you in moving it forward in both chambers.

What we know from the statistics reported by the Centers for Disease Control and Prevention ("CDC") – and especially what we do not know – tells the story of why this legislation is so critical. There are more than 4,500 Sudden Unexpected Infant Deaths ("SUIDs") in the United States each year, and half of these deaths are due to Sudden Infant Death Syndrome ("SIDS"). While it is suspected that 80-90 percent of the remaining deaths may be the result of unsafe sleep practices, we do not know for sure. The American Academy of Pediatrics recommends evidence-based safe sleep practices that include emphasizing: placing infants on their backs for sleep; using firm sleep surfaces in cribs with no soft objects or loose bedding; providing a smoke-free environment and room-sharing without bed-sharing. In order to further develop these and other safe sleep guidelines and to continue improving public education efforts around this topic, it is essential to have high-quality data on this important issue.

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Previously, this year, we joined with the following organizations in supporting this legislation: American Academy of Pediatrics, Child Prevention Injury Alliance, Safe States, Children's Hospital Association, Association of State and Territorial Health Officials, Association of Maternal & Child Health Programs, American Association of Nurse Practitioners and First Candle.

Once again, we strongly support the passage of S.314 and H.R. 669 on their merits and as a tribute to the career of the late Senator Frank Lautenberg. We look forward to working with your office to move this legislation forward. Thank you for your continued leadership in protecting our children.

Sincerely,

President and CEO

September 9, 2013

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Robert Menendez
United States Senate
528 Hart Senate Building
Washington, DC 20510

Dear Senator Menendez and Representative Pallone:

We write to thank you for sponsoring the Sudden Unexpected Death Data Enhancement and Awareness Act, and to express our strong support for it. The bill's original sponsor in the Senate, Frank Lautenberg, who recently passed away, was a champion for child safety throughout his career. Passing this legislation would significantly improve infant safety and would be a fitting tribute to his legacy. We are ready to join you in moving it forward in both chambers.

What we know from the statistics reported by the Centers for Disease Control and Prevention ("CDC") – and especially what we do not know – tells the story of why this legislation is so critical. There are more than 4,500 Sudden Unexpected Infant Deaths ("SUIDs") in the United States each year, and half of these deaths are due to Sudden Infant Death Syndrome ("SIDS"). While it is suspected that 80-90 percent of the remaining deaths may be the result of unsafe sleep practices, we do not know for sure. The American Academy of Pediatrics recommends evidence-based safe sleep practices that include emphasizing: placing infants on their backs for sleep; using firm sleep surfaces in cribs with no soft objects or loose bedding; providing a smoke-free environment and room-sharing without bed-sharing. In order to further develop these and other safe sleep guidelines and to continue improving public education efforts around this topic, it is essential to have high-quality data on this important issue.

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The public education and awareness role of the bill is also critical, because we know that public education can help reduce SUIDs. In 1994, the Back to Sleep public education campaign was launched by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"), now known as the Safe to Sleep campaign. This campaign has contributed to a significant decline in in SIDS deaths, but there is still an ongoing need for further progress that this bill's public education components would support. Finally, because there is nothing as tragic as parents having to plan a funeral for their baby, the expansion of support services, such as grief counseling, for families who have experienced a stillbirth or SUID loss is equally important.

Once again, we strongly support the passage of H.R. 669 on its merits and as a tribute to the career of the late Senator Frank Lautenberg. We look forward to working with your office to move this legislation forward. Thank you for your continued leadership in protecting our children.

Sincerely,

Amber N. Williams

Amber Norris Williams
Executive Director
Safe States Alliance
2200 Century Parkway, Suite 700, Atlanta, GA 30345
amber.williams@safestates.org| www.safestates.org
Phone: (770) 690-9000 | Fax: (770) 690-8996 | Mobile: (678) 895-5086

American Professional Society on the Abuse of Children

September 17, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone:

Please accept this letter as a formal endorsement from the American Professional Society on the Abuse of Children supporting the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We applaud your commitment to champion this bill in the wake of Senator Lautenberg's passing. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

If we can be of any assistance, please feel free to reach out to us at **mhaney@apsac.org** or 850-933-6915.

Sincerely,

Michael L Haney PhD, NCC, CISM, LMHC
Executive Director

Cc:
Viola Vaughan-Eden, PhD – APSAC President
Board of Directors

350 Poplar Avenue Elmhurst, IL 60126 Telephone: 630.941.1235 Toll Free: 877.402.7722 Fax: 630.359.4274
Web: www.apsac.org E-mail: apsac@apsac.org

Joint Letter in Support of H.R. 669

June 26, 2013

The Honorable Frank Pallone
237 Cannon House Office Building
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pallone:

We write to thank you for sponsoring H.R. 669, the Sudden Unexpected Death Data Enhancement and Awareness Act, and to express our strong support for it. The bill's original sponsor in the Senate, Frank Lautenberg, who recently passed away, was a champion for child safety throughout his career. Passing this legislation would significantly improve infant safety and would be a fitting tribute to his legacy. We are ready to join you in moving it forward in both chambers.

What we know from the statistics reported by the Centers for Disease Control and Prevention ("CDC") – and especially what we do not know – tells the story of why this legislation is so critical. There are more than 4,500 Sudden Unexpected Infant Deaths ("SUIDs") in the United States each year, and half of these deaths are due to Sudden Infant Death Syndrome ("SIDS"). While it is suspected that 80-90 percent of the remaining deaths may be the result of unsafe sleep practices, we do not know for sure. The American Academy of Pediatrics recommends evidence-based safe sleep practices that include emphasizing: placing infants on their backs for sleep; using firm sleep surfaces in cribs with no soft objects or loose bedding; providing a smoke-free environment and room-sharing without bed-sharing. In order to further develop these and other safe sleep guidelines and to continue improving public education efforts around this topic, it is essential to have high-quality data on this important issue.

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The public education and awareness role of the bill is also critical, because we know that public education can help reduce SUIDs. In 1994, the Back to Sleep public education campaign was launched by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"), now known as the Safe to Sleep campaign. This campaign has contributed to a significant decline in in SIDS deaths, but there is still an ongoing need for further progress that this bill's public education components would support. Finally, because there is nothing as tragic as parents having to plan a funeral for their baby, the expansion of support services, such as grief counseling, for families who have experienced a stillbirth or SUID loss is equally important.

Once again, we strongly support the passage of H.R. 669 on its merits and as a tribute to the career of the late Senator Frank Lautenberg. We look forward to working with your office to move this legislation forward. Thank you for your continued leadership in protecting our children.

Sincerely,

SAFE KIDS WORLDWIDE

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

CIPA CHILD INJURY PREVENTION ALLIANCE

CHILDREN'S HOSPITAL ASSOCIATION

astho™

SAFE STATES

AANP | American Association of NURSE PRACTITIONERS

AMCHP
ASSOCIATION OF MATERNAL & CHILD HEALTH PROGRAMS

First Candle
Helping Babies Survive & Thrive

savir
Society for Advancement of Violence and Injury Research

Society for Advancement of Violence and Injury Research
3416 Primm Lane ❖ Birmingham, AL 35216 ❖ 205/823-6106 ❖ savir@primemanagement.net

Friday, September 20, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from the *Society for Advancement of Violence and Injury Research* of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We applaud your vision to craft this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Regards,

Robert Ranieri
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Charlie's Kids
FOUNDATION

October 14, 2013

The Honorable Frank Pallone, Jr.
United States House of Representatives
237 Cannon Building
Washington, DC 20515-3006

Dear Representative Pallone:

Please accept this letter as a formal endorsement from Charlie's Kids Foundation of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We applaud your your vision to craft this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Sincerely,

Dr. Samuel Hanke
President, Charlie's Kids Foundation
sam.hanke@charlieskids.org

Betsy McCormack,
Secretary, Charlie's Kids Foundation
bmccorma@nycap.rr.com

www.charlieskids.org
www.twitter.com/Charlies_Kids
www.facebook.com/charlieskidsfoundation

A little more info about Charlie...
Charlie Paul Hanke was born April 6, 2010, to Sam and Maura Hanke. He was a healthy, beautiful baby boy! He brought incredible joy and happiness to his parents and to all of those he met. On the morning of April 28, 2010, Charlie died from SIDS. He was just three weeks old. Charlie's life was too short, but his impact has been huge. He is changing the lives and hearts of the people who hear his story. Through Charlie's Kids, our hope is that he will continue to make a difference and will be forever remembered. Charlie's Kids is a pending 501(c)(3) organization.

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SOMDI
Society of Medicolegal Death Investigators

November 14, 2013

The Honorable Frank Pallone, Jr.
237 Cannon Building
Washington, DC 20515-3006

Dear Rep. Pallone,

Please accept this letter as a formal endorsement from the Society of Medicolegal Death Investigators (SOMDI) of the Sudden Unexpected Death Data Enhancement and Awareness Act S314/HR669.

We appreciate your vision to craft this bill. The Sudden Unexpected Death Data Enhancement and Awareness Act will improve the collection of critical data to determine the causes of Stillbirth, Sudden Unexpected Infant Death (SUID) and Sudden Unexplained Death in Childhood (SUDC); increase education and awareness about how to prevent these tragedies in the future; and expand support services for families who have experienced a loss.

Julie Howe
President

Mr. PALLONE. And I wanted to mention that—because you mentioned law enforcement and, you know, their support for the bill—and I just wanted to mention that 3 of those in the 24, the National Association of Medical Examiners, the International Association of Coroners and Medical Examiners, and the Society of Medicolegal Death Investigators, are, you know, enforcement, just for your information.

But before I get to questions, Mr. Chairman, I wanted to address both you and the subcommittee for a moment. I just wanted to be sure to express my disappointment that the subcommittee didn't give the administration enough time to be here today to have input on these seven public health bills. As you know, many of the bills cross a number of agencies at HHS, and it is critical that they are able to give us their expertise on these proposals.

So I was going to ask if you could commit to me that we will arrange for some way to have the administration's technical views be heard by our staff and members.

Mr. PITTS. I am informed that we are in the process of getting technical information from the administration.

Mr. PALLONE. All right. And then, Mr. Chairman, I also wanted to enter into the record a statement by Congressman Bill Pascrell with regard to his bill, the Traumatic Brain Injury Reauthorization Act.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

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COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH

COMMITTEE ON THE BUDGET

Congress of the United States
House of Representatives

Statement for the Record
Congressman Bill Pascrell
U.S. House of Representatives Energy and Commerce Subcommittee on Health Hearing:
"Examining Public Health Legislation to Help Local Communities"
November 20, 2013

Chairman Pitts and Ranking Member Pallone, thank you for holding this hearing on these important public health bills. I am especially grateful that the Subcommittee will again examine the issue of traumatic brain injury and a bill I introduced, the Traumatic Brain Injury Reauthorization Act of 2013.

As the Co-Chair and founder of the Congressional Brain Injury Task Force, I have long advocated on behalf of both the civilian and military populations who struggle with the problem of brain injury. Since its founding in 2001, the Task Force's mission has been to expand the understanding and public awareness of brain injury. According to the Centers for Disease Control and Prevention (CDC), each year an estimated 1.7 million people sustain a traumatic brain injury (TBI). Unfortunately, TBI is a contributing factor to a third (30.5%) of all injury-related deaths in the United States. Beyond these numbers, TBI has become the "signature wound" of the wars in Iraq and Afghanistan, with 20% soldiers deployed are estimated to have experienced a brain injury. The brain injuries of our soldiers have spurred Congress to make unprecedented investments in brain injury research—research that will benefit soldiers and civilians alike for years to come.

As many of us here today know, TBI does not discriminate; it truly impacts all sectors of the population. Recent media reports have highlighted its impact on athletes, our service members and even a Member of this chamber, with former Congresswoman Gabrielle Giffords suffering a TBI in 2011 in the wake of a tragic shooting. Both the prevalence and complexity of these injuries call for more research.

The federal government must help address lagging public awareness of brain injury and its consequences and the relative lack of scientific knowledge we have about this ubiquitous injury. In Congress, we have been working tirelessly to correct both of these deficits. The Traumatic Brain Injury (TBI) Act, last reauthorized in 2008 and once again up for renewal this year, is the only federal law that specifically addresses the issues faced by the TBI community. The continuation of this program takes important steps forward in ensuring proper collaboration between civilian brain injury efforts and the work being done by the Department of Defense and the Veterans Administration. For example, the Traumatic Brain Injury Act established a CDC/NIH study, in collaboration with the DOD and VA, to identify the best methods of coordinating prevalence data, in order to ensure that national research takes into account the incidence of brain injuries among our nation's veterans and that current information about diagnosis and treatment are shared between the civilian and military scientific communities.

The TBI Act is an important tool providing for collaboration in the TBI research community, and care for those individuals who have suffered a TBI. The TBI Act currently authorizes:

- the Health Resources and Services Administration (HRSA) to assist States in developing and expanding service delivery capacity for individuals with traumatic brain injury and their families,
- HRSA to make grants for the Protection and Advocacy for Traumatic Brain Injury (PATBI) program, which provides critical advocacy services to ensure that people with TBIs live full and independent lives free from abuse and neglect,
- the Centers for Disease Control and Prevention (CDC) to conduct surveillance, prevention and public education programs, and,
- the National Institutes of Health (NIH) to conduct of basic and applied research in TBI.

I hope that as we continue to discuss the impact of TBI in the community, that the Congress will prioritize the reauthorization of this critically important legislation. In the last few years, we have learned more about the brain than we have over the last century. This knowledge should be applied to protect our fellow Americans. It is important to remember that these wounds may be invisible many times, but the consequences are very real.

Thank you.

Bill Pascrell, Jr.
Member of Congress

Mr. PALLONE. Thank you, Mr. Chairman.

Let me see, I wanted to start with Ms. Crandall. I don't know if I can get through all these, but I am going to try.

I wanted to thank you again for being here and, you know, sharing the heartwrenching story about the loss of your daughter Maria. And in your testimony, you also shared some sobering statistics that over 3,600 infants and 200 toddlers die suddenly each year. You noted that 26,000 women experience stillbirth. Clearly we need to do something to address this.

The Sudden Unexpected Death Data Enhancement Awareness Act that I sponsor contains provisions that will build upon the current CDC activities and ultimately help prevent these deaths from occurring. And I am sure I don't have to tell you that we are in a difficult fiscal climate. As much as I would like to advance all the provisions in H.R. 669, I recognize that that may not be feasible. So I just wanted to ask you, in light of these constraints, what do you believe are the most important areas or provisions for us to address?

Ms. CRANDALL. I strongly feel that the most important areas are the comprehensive investigations that would then allow for effective surveillance and then public awareness and intervention strategies. I think if we don't fix the issue of these cases initially being investigated thoroughly, we will never have the good data that will then later on help public health and research, and as well as these families on an individual basis. But there are many efforts going on right now that have huge obstacles in front of them because they are dealing with broken data. I think we need to go back and prioritize the investigations.

Mr. PALLONE. All right. Thank you so much really again for your testimony and all your support in getting this moved.

Dr. Nagele, if I could ask you, in your testimony you discussed movement of State TBI and protection and advocacy programs currently administered by the Health Resources and Service Administration to the Administration for Community Living, and you noted this would help foster greater collaboration between TBI and aging and disability programs.

You also cited some additional benefits of a potential reorganization. For example, you mentioned greater collaboration on TBIs among older adults resulting from falls.

Can you elaborate on how movement of TBI programs to ACL will be beneficial for individuals with TBI and their families?

Mr. NAGELE. Yes. We believe that elevation to the ACL will help people across the age span to better recognize the effects of brain injury and to coordinate with the many services that sit within ACL, within intellectual disabilities and with aging, and that this opportunity will actually give more ability to leverage with other existing programs.

Mr. PALLONE. All right. Thank you.

I think I am going to get in all three questions.

Mr. STACK. Dr. Stack, you know, I have been involved with NASPER for a long time with Mr. Whitfield. It is clear from your testimony that NASPER and other prescription drug monitoring programs, or PDMPs, are an important tool in helping to address the problem of nonmedical use of prescription drugs.

As you know, State PDMPs collect, monitor, and analyze information on scheduled or controlled prescription drugs. You noted PDMPs provide valuable info for physicians, pharmacists, and other health providers to support appropriate prescribing and treatment for pain management. And you also mentioned the importance of NASPER's public health focus.

So if I could ask you, why do you believe the public health focus of NASPER is so important, and how does that differ from the emphasis of other monitoring programs?

Mr. STACK. Well, I would say there is a difficult balance between two different issues here. One is treating patients who have pain. And the Institute of Medicine estimates there are as many as 100 million Americans who live with chronic daily pain that is inadequately treated. And then the difficulty of an epidemic, and I think we would all agree it is an epidemic, of prescription drug abuse and the horrible damage and devastation that causes.

So it is a public health magnitude kind of problem, because we have to address competing needs in society, the treatment for one, which has grave consequences when misapplied or misused for other folks.

We would suggest that it is a public health as opposed to principally a public justice issue or a legal issue, because these are our fellow men and women and children who require treatment and care for various problems and maladies. And we believe very strongly that it is a health-related issue, that if we attend to that particular concern and work together as a society, we will get far further in helping our fellow men and women than incarcerating them all and pursuing them through the justice system. So we can't emphasize strongly enough that we believe the health-based approach is the proper approach.

Mr. PALLONE. And I appreciate that. That is very helpful. Thank you very much.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from Kentucky, Mr. Whitfield, 5 minutes for questions.

Mr. WHITFIELD. Well, thank you, Mr. Chairman. And I would like to thank all of the witnesses for joining us today and giving your views on this important legislation.

Dr. Stack, I would like to follow up on the prescription drug monitoring programs as well. As you know, the first program came out of the Appropriations Committee and was placed over at the Department of Justice and was primarily focused on law enforcement issues, abuse. And then Mr. Pallone and I and others, Mr. Pitts and others, authorized the national Prescription Drug Monitoring Program. And as you have indicated in your testimony, ever since we started the program we have had difficulty getting the necessary appropriations, and we still are having difficulty doing that. We tried to merge the programs, and we have had some difficulty even doing that.

But I guess the good news is that it is my understanding that now 47 States do have a prescription drug monitoring program. Certainly they are not all the same. But in your testimony, I think you referred to in Ohio in the emergency rooms, that you said 40

percent of providers, based on information they have received on the prescription drugs, change their prescription orders.

Mr. STACK. Right. So in that particular study they found that 43 percent of prescribers produced less or prescribed no opioids at all based on the information they received.

There is a second side to that, though. When I and my colleagues practice, there are quite a number of times when we look in the database and find that a patient has received no opioids ever. And in fact that helps to validate and help us to feel more comfortable that a short course of treatment is appropriate——

Mr. WHITFIELD. Right.

Mr. STACK [continuing]. In that patient. It helps both ways.

Mr. WHITFIELD. Well, do you feel that the KASPER program in Kentucky is doing well or do you have any suggestions of how we could improve it or——

Mr. STACK. So the KASPER program in Kentucky has come a long way. As recently as 2011, there were strong prohibitions in who could see it, who could share it——

Mr. WHITFIELD. Right.

Mr. STACK [continuing]. Enter it into the medical record. That has rapidly evolved, as you know, with House Bill 1 in the State of Kentucky and then the legislation the following year, in 2013, that made some corrective actions. So I would say that the KASPER program in Kentucky is evolving well.

It did teach and show, I believe, something we feel strongly about, which is these tools are so rapidly evolving and are so uneven and heterogeneous across the country that mandating the use of these programs is not the appropriate approach; that, in fact, if we would work to standardize them, make them interoperable, and have realtime data, meaning I ask the database for an answer and I get it quickly, that the clinicians will use these tools when they function well. And we are only just beginning down that path.

Mr. WHITFIELD. So you don't think mandating is necessary then?

Mr. STACK. I don't think so. I think with countless other things, physicians have shown when the technology works and helps patients, we adopt it——

Mr. WHITFIELD. Yes.

Mr. STACK [continuing]. And when it is broken and doesn't work, we generally don't find it useful.

Mr. WHITFIELD. Yes.

Mr. STACK. We are getting to a better place. But NASPER is essential, because the States are so all over the map for the immaturity of their programs and the fact that they don't communicate with each other yet——

Mr. WHITFIELD. Right.

Mr. STACK [continuing]. That the relatively small investment on the Federal Government could help to jump start a profound evolution in advancement in these programs.

Mr. WHITFIELD. Yes. Well, I really appreciate your taking time to come up and talk about it. As I said, we appreciate the issues that all of you have discussed. And as we move forward, Dr. Stack, maybe we could get together sometime and get some additional ideas from you on ways that we can try to merge these programs

so that they can be as efficient and technologically advanced as possible.

Mr. STACK. The AMA is definitely committed to working on this issue, and we would be happy to do that.

Mr. WHITFIELD. Thank you so much.

Oh, I yield to Dr. Burgess.

Mr. BURGESS. Oh, I am sorry. I have to leave.

Mr. WHITFIELD. Oh. OK. Got to leave.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green, for 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

And I want to thank our panelists and thank the Chair and the ranking member for listing this number of bills on our schedule for today, because each of them address a certain part. And some of us who have been on the Health Subcommittee for years have dealt with these before, and, again, we appreciate your time this afternoon.

And I would like to thank Mr. MtJoy for taking time to testify for the Family Health Care Accessibility Act, which would greatly benefit health centers and their patients. That just happens to be the one that Congressman Murphy and I have been working on. It seems like this is our third Congress. We passed it out of the House twice, and the Senate hasn't taken it up.

In your testimony, you mention issues facing community health centers regarding recruitment and retention of healthcare providers. There are programs like the National Service Health Corps, but even the current number of National Health Service Corps scholarships and awards, there is a primary care shortage. Can you give us some examples of why health centers have difficulty retaining or recruiting providers?

Mr. MTJOY. Well, even with the recent investments in expanding the National Health Service Corps, the demand still outpaces the supply of healthcare providers. And this is particularly true in rural areas, such as where I am from. Healthcare providers generally aren't from rural areas, whereas we try a number of initiatives to what I will call grow your own. Certainly recruitment and retention is one of the largest or most challenging areas of providing healthcare, certainly for us.

Mr. GREEN. And I know there are a lot of programs over the years have tried to encourage, you know, loan forgiveness and things like that to have physicians go to rural areas. How will the Family Health Care Accessibility Act help health centers meet that growing demand for primary health care?

Mr. MTJOY. Well, again, it will expand our provider base. And as we struggle to meet the demands of our patients, recruitment and retention of providers, expanding our primary provider base is one more method of helping us do that.

Mr. GREEN. And I know, I represent a very urban area in Houston, Texas, and our federally qualified health centers have some of the same challenges, even though we have three medical schools within 50 miles, of attracting primary care physicians. You stated that one untapped resource for meeting the demand for primary care is volunteers, and especially retiring or retired health practi-

tioners. If Congress were to pass the Family Health Care Accessibility Act, what type of practitioners would you hope and expect to volunteer their time in your health centers?

Mr. MTJOY. Well, I have spent or focused most of my attention on physicians, but in addition to physicians, for instance at Cornerstone Care and other community health centers across the country, this also includes nurse practitioners, physician assistants, dentists, licensed social workers, et cetera. So, again, it crosses the gamut of provider types.

Mr. GREEN. And I have always said if I can get a primary care or a person, not even a volunteer, into community health centers, they would know they can actually practice medicine and maybe make a decent living for their families.

Can you explain to the members of the subcommittee how training in health centers increase the likelihood that an individual would be more likely to stay in the community where they complete their training?

Mr. MTJOY. Well, absolutely. We try to expand our provider base by providing training opportunities for a variety of disciplines that I have just mentioned, from PAs to nurse practitioners, et cetera. Recently Cornerstone Care became one of the new teaching health centers, and we have got our first class of residents now in the program and recruiting our second.

We have found that when healthcare providers, particularly physicians, do their training or part of their training at community health centers, they are two-thirds more likely to return to that type of practice following their training.

Mr. GREEN. OK. Thank you, Mr. Chairman. I will yield back a few seconds. But again, thank you for scheduling this bill today.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. I, too, am very appreciative of the fact that we have all of these witnesses here, and the testimony that you gave on each of the various issues was very important and enlightening.

Mr. Chairman, I will take a minute to talk about Lyme disease and ask a question of our witness on that, Ms. Smith. But Lyme disease is a growing problem throughout our State, but it is endemic in northern Virginia. Our representatives from the local, State, and Federal levels are working aggressively to raise awareness about this issue for our citizens and medical providers to encourage prevention, quick diagnosis, and treatment. My colleagues and I in the Virginia delegation, particularly Congressmen Frank Wolf and Rob Wittman, appreciate you having this hearing. I should also mention that Barbara Comstock is working on this in the Virginia House of Delegates, as well.

Ms. Smith, H.R. 610 requires that Tick-Borne Diseases Advisory group include members that represent State and local healthcare professionals, individuals who have firsthand experience with tick-borne disease, and representatives of a tick-borne voluntary organization. How do you think this will help to enhance communication amongst the Federal agencies?

Ms. SMITH. Well, I think, unfortunately, what has happened right now is oftentimes what I see is that the agencies—now, they are trying to do a good job in their area, but it is not always communicated into other areas as to what kinds of projects they are doing. Plus, there is really not a national strategy to attack tick-borne diseases. And so over the 30 years what I have seen, the numbers have grown, you know, greatly, the numbers of ticks, the numbers of diseases.

And so if you put people on there who have perspectives—for example, we have no clinical treating physicians have a perspective right now, are able to give their perspective to the Federal Government about what research projects they feel are important. They are seeing a lot of people with very serious chronic Lyme disease, which is different than just getting a tick bite and getting, you know, a few weeks and getting better.

So they are seeing people with these debilitating symptoms. They have all this knowledge that they have gleaned from many years of treatment, and they are able, for example, to look at the results of Lyme disease testing, and sometimes, even though the test may come back and it says it is negative, they are able to read the bands from their clinical experience and determine, yes, these people really do have Lyme disease and they require extensive treatment.

And so they would be able to take this kind of knowledge, because one of the biggest factors, and I think everybody agrees on this, we need testing that is, you know, a gold standard. We don't have that now. We are missing so many patients, and they go on to develop these intense symptoms that are not only causing them a lot of health disability, but are also causing obviously great, tremendous costs to their families, to the government, et cetera.

So if the clinicians could provide their input, it would be a better chance that we could get diagnostic tests. Also, tests need to be found that will determine whether someone has active infection.

Mr. GRIFFITH. And you believe that this bill will help that. And I do appreciate it and appreciate your testimony. I am going to move on to another subject, because, unfortunately, while I would like to talk to each one of you, I only have a few minutes.

That being said, I will move to the NASPER bill and pick up where Congressman Whitfield left off. It is a very serious issue in lots of the country. It is particularly a serious problem in my district in southwest Virginia. A study done there by the United States Attorney's Office for the Western District of Virginia found serious problems, that this was a major impact on our region.

And the study also cited that just four counties, which have 1 percent of Virginia's population, accounted for the Virginia State Police spending 25 percent of their statewide undercover purchase funds buying prescription medications in those four counties. Likewise, the chief medical examiner's office in Roanoke says that deaths are up by 40 percent as a result of the activities with prescription drugs.

Doctor shopping contributes to this spread. I think we need to do more to prevent this practice, which is why I support the lock-in mechanism that many private insurers are utilizing, and I think that would be helpful.

Dr. Stack, is there anything you would like to in 23 seconds tell us what you didn't touch on when you were answering Mr. Whitfield?

Mr. STACK. No. We share that this is critical, but you just touched in your own testimony how it is a variable problem that affects different communities more intensively, which is why we don't believe a one-size-fits-all for some of the other strategies is appropriate, because it will misapply strategies in some areas and under-apply them in different places. So we believe NASPER, everyone agrees, all the stakeholders agree these PDMPs are an essential tool. The other strategies, we could have a longer discussion another day about where they may be best applied.

Mr. GRIFFITH. I appreciate it very much. And with that, Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. LANCE. Thank you very much, Mr. Chairman. Good afternoon to the panel.

To Dr. McCabe, the Senate bill, the companion bill, contains a priority review process for nominating new diseases that meet certain criteria. Would you please discuss with us this provision and its impact on the screening process and the health of children.

Mr. MCCABE. Yes. That is a difference between the two bills. We feel that it is important as the March of Dimes that there be timely, swift consideration of new entities, and these were submitted from the Secretary's Advisory Committee. So there needs to be rigorous scientific integrity around that, but we do feel that there needs to be swift movement once action is taken by the Secretary's Advisory Committee.

Mr. LANCE. Thank you.

We are hearing increasingly that in the not-too-distant future, next generation DNA-based sequencing may allow the rapid analysis of a newborn's genome, possibly replacing some or even all of the current newborn screening techniques that rely on biochemical changes in the blood. Do you see that is happening in the near term and do you have any thoughts on the advantages or disadvantages of genome sequencing compared to current techniques?

Mr. MCCABE. That is something I have watched very closely, because my lab was the first to show that you could get DNA——

Mr. LANCE. Yes.

Mr. MCCABE [continuing]. From the newborn screening spots. The NIH has funded, both NHGRI and NICHD, have funded four institutions to look at this problem, not only to look at the technology and can you sequence in a reliable fashion from the DNA in the newborn screening, but all of the ethical, legal, social implications, and policy issues around that. So I think this is important work that you bring attention to, and it is being funded now by two institutes that are heavily invested in this, and we are all looking forward to the results.

Mr. LANCE. Do you think that H.R. 1281 should be altered in any fashion to take into account what we were just discussing?

Mr. MCCABE. I think that the research has just begun. Those are 5-year research projects that were just established. I think there

would be opportunities in the future. Certainly I think it is important to recognize that there may be other technologies, such as DNA sequencing, that will come along.

I think it is also important to recognize that there is NICHD authorization for funding for the project to continue to develop new technologies in the future. But, yes, it should encompass new technologies, but I think that is one of the things that the Secretary's Advisory Committee would allow. It allows the community to be nimble if new technologies do come along.

Mr. LANCE. Thank you very much.

To Dr. Ford, can you point to a specific example of a situation where a poison center's being located within a community or geographic area has benefited public health surveillance?

Ms. FORD. Yes. Well, first of all, I think that in many ways with regard to emergency preparedness planning, working with EMS, the public health outreach, the education of the healthcare providers in a region that are done through the regional poison center are very, very important. It was one study done that showed that as the distance between a poison center and the caller increases, it is less likely that that caller is going to call that poison center.

Mr. LANCE. Yes.

Ms. FORD. And I believe that that probably needs to be studied further, but I believe that it is true that you are more likely to use a service that you are more intimately associated and familiar with.

Mr. LANCE. Thank you to this very distinguished panel. And I yield back the 30 seconds I have.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the questions of the members present. Other members will have questions, and we will have some follow-up questions. We will submit those to you in writing. We ask the witnesses to please respond promptly.

Thank you very much. This has been very important information, very important issues. We thank you for coming today.

I remind members that they have 10 business days to submit questions for the record, and that would be by the close of business on Friday, December 6th.

Thank you very much for your attendance.

Without objection, the subcommittee is adjourned.

[Whereupon, at 4:28 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of Chairman Fred Upton
Health Subcommittee Hearing on "Examining Public Health Legislation to Help Local Communities"
November 20, 2013

Since the start of this Congress, one of the major priorities of the committee has been helping and protecting families and local communities. Back in southwest Michigan and all across the country, families and local communities expect those of us in Washington to work together to solve problems, especially on issues affecting public health.

I'm proud to report that, because of the hard work and dedication of the members of the Energy and Commerce Committee, we have been able to send six public health bills to the president's desk that will help American families and communities. These include H.R. 307, the Pandemic and All-Hazards Preparedness Reauthorization Act; S. 622, the Animal Drug and Animal Generic Drug User Fee Reauthorization Act; S. 252, the PREEMIE Reauthorization Act; S. 330, the HOPE Act; H.R. 2094, the School Access to Emergency Epinephrine Act; and most recently, H.R. 3204, the Drug Quality and Safety Act. Together, these bills will make a significant difference in Americans' lives and improve public health in this country.

Today's hearing is an opportunity to build on our bipartisan success as the subcommittee examines legislation to further improve the lives of our constituents and their families. These bills involve prescription drug abuse, poison control centers, liability protection for volunteer health care professionals at community health centers, newborn screening, Lyme Disease, sudden unexpected death of infants, and traumatic brain injuries.

These are important issues, and working together, we can continue to make a difference. I thank those members both on and off the committee who have worked on the bills we will review today.

I thank the witnesses for attending today's hearing, and I look forward to their testimony and recommendations.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
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Minority (202) 225-3641

December 13, 2013

Dr. Marsha Ford
President
American Association of Poison Control Centers
515 King Street, Suite 510
Alexandria, VA 22314

Dear Dr. Ford:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 20, 2013, to testify at the hearing entitled "Examining Public Health Legislation to Help Local Communities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your response to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, January 7, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

American Association of Poison Control Centers
Questions for the Record to the Energy and Commerce Committee
January 7, 2014

Dear Congressman Engel:

Q1. I know that a majority of the calls poison control centers take come from concerned citizens, but will you tell us what role poison control centers play for health care providers?

A1. Physicians, pre-hospital providers, nurses, pharmacists and other health care providers call poison centers for assistance with triage, diagnosis, treatment and disposition of patients with known or suspected poisoning. Initial toxicological information to determine the type and effects of poisoning and the recommended treatment protocol is most commonly provided. Toxicology consults are also requested for more difficult or unusual cases. For most healthcare providers, calling the poison center provides the only access to board-certified medical toxicologists. This access represents virtual regionalization of toxicology expertise for poisoned patients, "ensuring that the right patient gets to the right hospital at the right time and receives the right care."

Poison center assistance has been found to reduce the length of stay for hospitalizations due to poisonings. Treating poisoning patients requires extensive specialized knowledge that not all health care providers can be expected to possess and maintain. Poison centers give health care providers an independent source of clinical information on the effects of poisonings and the best practices for treatment. Poison centers may interface with health care providers in either of two situations. First, if the initial caller is a member of the general public and if the reported exposure warrants medical care, the poison centers may refer the exposed person into a health care facility; in these situations, poison centers call ahead to the health care facility to report an en route patient and follow the patient at the health care facility until resolution of the acute event. In the second situation, calls about an exposed patient may originate from a health care facility; cases originating from health care facilities increased 0.7 percent in 2012, to 19.5 percent.[1]

Site of Call and Site of Exposure, Human Exposure Cases[1]

	Site of caller		Site of exposure	
Site	**N**	**%**	**N**	**%**
Residence				
Own	1,614,433	70.96	2,074,514	91.18
Other	35,189	1.55	54,261	2.38
Workplace	24,787	1.09	35,973	1.58
Health care facility	**443,719**	**19.50**	7,132	0.31
School	10,396	0.46	28,578	1.26
Restaurant / food service	544	0.02	4,931	0.22
Public area	7,179	0.32	21,471	0.94
Other	131,215	5.77	24,447	1.07
Unknown	7,679	0.34	23,834	1.05

1. *Table 10.* Management Site of Human Exposures. Adapted from "2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 30th Annual Report," by J. B. Mowry, PharmD; D. A. Spyker, PhD, MD; et al., 2013, *Clinical Toxicology.*

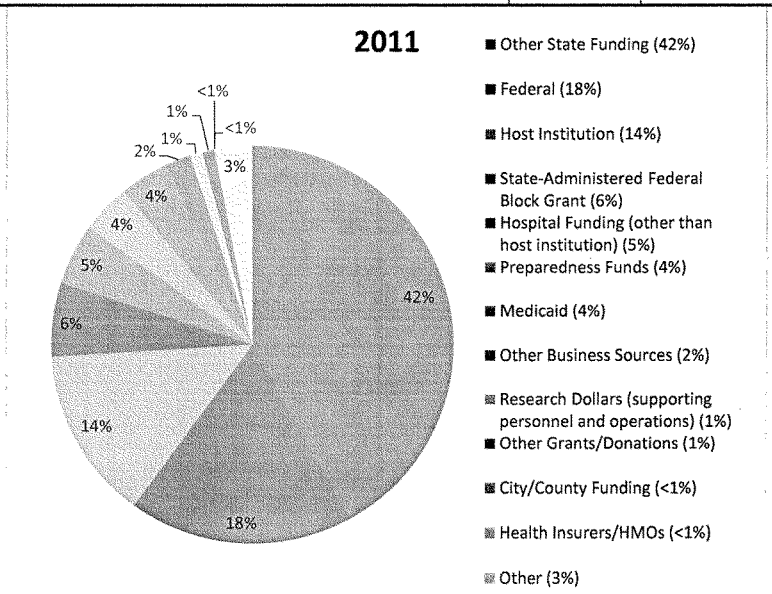
American Association of Poison Control Centers
Questions for the Record to the Energy and Commerce Committee
January 7, 2014

Q2. Will you tell the Committee how your center obtains the funding necessary to staff its center 24 hours a day, seven days a week, 365 days a year?

A2. Poison centers obtained funding for FY2011 by way of three main sources: federal HRSA grants, state and local government funds, and private funds.

In 2011, state and local government funds (excluding state-administered block grants and Medicaid) were the primary source of funding, followed by private funds and federal HRSA grants (federal HRSA grants of $18.6 million, less 8 percent for administration which equals $17.1 million – only 13 percent of the $136 million total). All remaining public funds (federal, state, county and city) were included in state and local government funding.[2]

Source of Funding[2]	%	Amount in 2011 (in millions)
Federal HRSA Grants *(excluding administration)*	13%	$17.1
State and Local Government Funds *(including preparedness funds, Medicaid, State-Administered block grants and other state, city and county funding)*	62%	$83.8
Private Funds *(including hospital, host institution, research, grants, donations, health insurers, HMOs and other business funds)*	25%	$35.1
Total	**100%**	**$136.0**



2. American Association of Poison Control Centers. (2012). *Final Report on the Value of the Poison Center System.* Washington, D.C.: The Lewin Group, Inc.

American Association of Poison Control Centers
Questions for the Record to the Energy and Commerce Committee
January 7, 2014

Q3. Will you please discuss how poison centers have been impacted by this challenging fiscal environment and why reauthorizing this program in a timely manner is important?

A3. In April 2011, the federal government voted to cut funding for poison centers by about 25 percent; in December 2011, Congress again cut poison center funding by an additional 14 percent. These cuts came on top of budget cuts at the state level. Some poison centers have experienced a decrease in funding from all sources of more than 40 percent, making it difficult to continue providing services.

Unfortunately, poison center funding may be on the block again as federal and state governments develop upcoming budgets. Without this funding, most poison centers would become unstable and probably be forced to close.

With these recent funding reductions, poison centers reported that they were required to scale-back services across the board and specifically to the areas of hospital preparedness, environmental disease detection, personnel, travel, materials and education/outreach services. All poison center managers reported budget deficiencies and shared concerns about the elimination or reduction in services that occur if funding issues were not adequately addressed.[2] At this time, several poison centers providing sole service to their heavily populated states are facing serious threats of closure or partial loss of core functions, due to lack of adequate funding.

2. American Association of Poison Control Centers. (2012). *Final Report on the Value of the Poison Center System*. Washington, D.C.: The Lewin Group, Inc.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225-2927
Minority (202) 225-3641

December 13, 2013

Dr. Steven J. Stack
Immediate Past Chair
Board of Trustees
American Medical Association
25 Massachusetts Avenue, N.W., Suite 600
Washington, D.C. 20001

Dear Dr. Stack:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 20, 2013, to testify at the hearing entitled "Examining Public Health Legislation to Help Local Communities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your response to that question in plain text.

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Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

AMA
AMERICAN MEDICAL ASSOCIATION

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January 7, 2014

The Honorable Joseph Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the physician and student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the additional questions submitted by Representatives Ed Whitfield and Kathy Castor as part of the Committee on Energy and Commerce Subcommittee on Health's hearing entitled, "Examining Public Health Legislation to Help Local Communities." For ease of reference, I have included the questions transmitted in your letter along with the responses below. The AMA applauds your leadership in working to ensure passage of H.R. 3528, the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013" (NASPER 2013). In short, passage of NASPER 2013 and full appropriations are urgently needed to ensure that physicians across the country have patient specific information at the point-of-care as part of their workflow to combat prescription drug abuse while ensuring patients with the legitimate need of pain management continue to have access to medically necessary care. With the telecommunication and related technological advances we are experiencing—which can be implemented when funded adequately—prescription drug monitoring programs will be able to offer individualized information to support clinical decision-making as well as population based data to establish a public health set of solutions and education programs for prescribers, state policy-makers, and the impacted communities.

Questions Posed By the Honorable Ed Whitfield

1. According to a recent report by the Department of Health and Human Services, drug overdose rates have increased five-fold since 1980, and in 2009 drug overdose deaths outnumbered those of motor vehicle crashes for the first time in U.S. history. Would you elaborate on the reasons why we have seen such an alarming increase in overdose deaths? Apart from the tragic deaths that occur as a result of drug overdose, what other impacts does this problem have on our health care system?

   Drug overdose deaths include illicit drugs and a wide variety of prescription drugs, many of which are not controlled substances. In 2010, 57 percent of overdose deaths involved pharmaceuticals. Of these, approximately 75 percent were unintentional, 17 percent were suicides, and the rest were undetermined. Opioids (75 percent), benzodiazepines (29 percent), antidepressants (18 percent), and antiepileptic and antiparkinsonism drugs (8 percent) were the pharmaceuticals, alone or in combination, most commonly involved in prescription drug-related overdose deaths.

   The increase in prescription drug overdose death corresponds to the rise in overall prescribing rates and diversion and abuse of prescription drugs, particularly certain opioids, coupled with a lack of treatment options for those suffering from addiction, and correspondingly low awareness and use of

overdose prevention options, such as naloxone in community-based settings. It also reflects that until relatively recently, most physicians and county and state health regulators and policy-makers have not had access to robust epidemiological data to identify doctor-shoppers, prescriber-specific information, and trends in local and regional areas. The availability of this information to prescribers, dispensers, and public health policy-makers would support individualized prescribing, as well as targeted educational and regulatory policies based on specific needs of local and state jurisdictions. While there is a national public health crisis, local and regional jurisdictions face different causes, challenges and patterns of abuse, diversion, overdose and death. NASPER 2013 will provide support for prescription drug monitoring programs that are proven to provide data that can be used by prescribers and public policy-makers and regulators to implement targeted policies rapidly as this epidemic of addiction evolves.

This overdose trend is exacerbated by the limited access to existing options to treat prescription drug addiction, limited patient resources or insurance coverage for such treatment, and equally low awareness of where to go for help among many who suffer from addiction. The availability of in-patient programs to treat prescription drug addiction is far exceeded by the number of individuals requiring such treatment. Unfortunately, despite efforts to increase the number of physicians who offer out-patient treatment, the number participating in such programs remains far too low to meet the existing and growing need of individuals requiring such medical care. Low awareness among physicians may be one factor for the current participation rates, but other factors that have been raised include the regulatory requirements and interactions with a law enforcement agency—the Drug Enforcement Administration (DEA) —which conducts onsite unannounced audits without regard to the operations of a medical practice which can be highly disruptive to scheduled patients—including those in practices where the majority of the patients are not receiving medical care for addiction.

The costs of prescription drug overdose to the health care system are significant as treatment for overdose typically will occur in hospital emergency departments—the frontlines of many public health crises. Unfortunately, there remain far too few treatment programs and out-patient providers available to reverse the current trend of addiction. Considerable effort and resources must be invested to rapidly and safely increase the availability of addiction treatment programs. The number of unintentional overdoses has increased in a parallel fashion with the estimated number of emergency department visits and the number of patients seeking substance abuse treatment of opioid dependence and addiction. In addition to the direct health care costs shouldered by hospitals in the emergency department, including uncompensated care for patients who need to be stabilized but do not have health insurance or financial resources, the indirect costs, while more difficult to quantify, are no less significant or important. These are costs borne by other patients who have delayed treatment and access to medical services in emergency departments or hospital in-patient care.

2. Reports have shown that there is a correlation between opioid-related morbidity and mortality and the prescribing and dispensing of opioid analgesics. Would you discuss the factors surrounding the rise in opioid prescribing we have seen in recent history? What are some of the issues physicians face when approached by patients who are seeking treatment for pain? How do we balance the need to ensure access to pain treatment for those who legitimately need it with stemming the epidemic of abuse we are faced with?

There are a host of factors that have led to the rise in opioid prescribing. The last 15 years have seen a greater emphasis on managing pain as 2001-2010 was declared the "Decade of Pain Control and Research," the Joint Commission on Accreditation of Healthcare Organizations' (Joint Commission) standards were implemented mandating an aggressive evaluation and treatment of patient-reported pain, and patient satisfaction surveys on pain have assumed an increasing role in prescriber and hospital evaluation. Other major factors include the rise of criminal syndicates running pill-mills, as well as the systematic lack of access to mental health services, which is significant factor for the most at-risk population abusing prescription drugs.

In 2001, the Joint Commission made pain management a condition of accreditation. Those facilities that fail to follow the requirements risk their accreditation. Even with this emphasis, there is evidence that there remains systemic under-treatment of pain. As a result, in 2010 as part of the Affordable Care Act (ACA), the U.S. Department of Health and Human Services (HHS) was required to commission a report from the Institute of Medicine (IOM) to examine pain as a public health problem. In 2011 the IOM issued the report with a recommended action plan that emphasized a population-level prevention and management strategy. The IOM called for improved data to ensure that the groups of people currently underdiagnosed and undertreated were provided appropriate medical care and encouraged federal and state agencies and private organizations to accelerate the collection of data on pain incidence, prevalence, and treatments. It is estimated that nearly one-third of people will experience chronic pain at some point in their lives. As the Baby Boom portion of the population ages, the need to appropriately address pain management needs will only grow. Prescription drug monitoring programs that emphasize a public health approach dovetail with efforts to identify those inappropriately seeking prescription drugs for non-medical uses, while ensuring those who have legitimate need of pain treatment receive medically necessary care. The pressure to appropriately treat pain has increased since underprescribing pain medications is considered as inappropriate as overprescribing. For example, there are media reports that the Oregon and California medical boards have disciplined physicians for undertreating pain, and New Mexico revised its medical practice act to specify that under-treatment may be grounds for unprofessional conduct.

A second major factor involves criminal actors. With the advent of higher potency and long-acting opioid analgesic products, a number of high-volume "pill mills" have emerged in various states, contributing to the doubling in opioid analgesic use, which has occurred over the last decade. The DEA has documented the ability of these criminal syndicates to move from one state to another once the federal government and local jurisdiction implement effective enforcement strategies to shut-down these criminal enterprises that enlist unscrupulous prescribers and/or dispensers in illegal conduct. Continued coordinated efforts among the DEA and local jurisdictions to combat pill mills will remain essential as such individuals are not interested in educational opportunities or information on doctor shoppers at the point-of-care to inform clinical decision-making.

Finally, another significant factor involves the lack of access to mental health services. People with mental health disorders are at increased risk for heavy therapeutic use, non-medical use, and overdose of opioids. The Center for Disease Control and Prevention (CDC) analysis highlights the frequent involvement of other drugs typically prescribed for mental health conditions in overdose deaths. According to HHS, in 2012, nearly 91 million adults lived in areas where shortages of mental health professionals made it hard to obtain treatment. HHS told Congress this year that 55 percent of U.S.

counties have no practicing mental health professionals. And even in well-served areas, demand is so high that it can be difficult for new patients to be accepted by a provider.

Developing a public health-based approach to harmful drug use requires having treatment services available for those with substance use disorders, including addiction. Between 2004 and 2012, the number with opioid analgesic dependence or abuse increased from 1.4 million to 2.1 million and the number of persons with heroin dependence or abuse in 2012 (467,000) was approximately twice the number in 2002 (214,000). In 2012, only about 11 percent of those persons aged 12 or older needing treatment for an illicit drug problem received treatment in a specialized facility. Among those who reported that they believed they needed treatment for their illicit drug or alcohol use problem, the primary reason for not receiving treatment was a lack of insurance coverage and inability to pay the cost.

Reductions in the supply of prescription drugs, however, may be a key factor in the unintended yet tragic, consequence of increases in illicit drug use—most commonly, heroin. Heroin is a less expensive yet more potent opiate. According to the National Survey on Drug Use and Health, "[t]he number of persons who were past year heroin users in 2011 (620,000) was higher than the number in 2007 (373,000)." The AMA urges Congress, as it considers strategies to curb inappropriate use of prescription drugs, to support efforts to address the need for the prevention of illicit drug use and the treatment of those who are addicted. Just addressing the supply will not by itself solve the problem of demand and could drive an unintended increase in overdose and death.

3. & 4. Combined Answer. According to the Department of Health and Human Services HHS, one of the most promising clinical tools to address prescription drug abuse are state PDMPs. These programs are designed to monitor prescribing and dispensing of controlled substances and can provide a prescriber or pharmacist with critical information regarding a patient's prescription history. Why have PDMPs been successful in curbing abuse of prescription drugs? Would you describe for the Committee how these PDMPs function and what role providers play within the system? What are the biggest challenges faced by stakeholders, such as states, providers, and pharmacies when it comes to PDMPs?

4. According to the Department of Health and Human Services, as of July 2013, 47 states had operations PDMPs. However, they are significantly underutilized by providers. A number of factors contribute to this underutilization, including cumbersome nature of accessing current systems and privacy concerns. Would you elaborate on some of the factors that may lead to underutilization of PDMPs? What steps can be taken to increase prescriber usage of PDMPs? States such as Kentucky and New York have actually passed laws requiring prescriber registration and utilization of PDMPs. What is your take on this approach?

In 2005, NASPER was signed into law. Although millions were authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMPs. In theory, PDMPs were to provide reliable and actionable information. In reality, however, it has been only in the past couple of years that most states have finally passed state legislation establishing PDMPs, and the majority of PDMPs are not real-time, interoperable, or available at the point of care as part of a physician's workflow. Only five states provide data within 24 hours, according to the National Alliance for Model State Drug Laws (NAMSDL); one state provides data within three days,

32 states take up to a week to provide data, and nine states take between two weeks and one month. With respect to interstate interoperability, NMSDL reports that 43 states can legally share data across state lines, but only 20 can legally share data with other PDMPs. Continued support for interstate interoperability will help move this issue forward.

PDMPs need to be adequately funded, maintained and modernized to ensure their long-term ability to help combat prescription drug abuse, misuse and diversion. The Congressional Research Service estimates that PDMP costs may vary widely, with start-up costs ranging from $450,000 to over $1.5 million and annual operating costs ranging from $125,000 to nearly $1 million. There is a pressing need right now for Congress to appropriate funding for NASPER, but state and private funding will be needed to maintain and undertake much needed upgrades and modernization of PDMPs. The AMA continues to strongly advocate for federal and state funding to ensure PDMPs have the support they need.

In the instances when PDMPs have been adequately maintained and funded, are available at the point-of-care with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned. This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances.

Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs. There is an immediate need to upgrade existing PDMPs and to ensure that prescribers have appropriate latitude to assess when consultation is needed. For example, while it makes sense for a pain medicine specialist to regularly consult a modernized PDMP that provides comprehensive, accurate data for his or her patients to review patient compliance and the potential for doctor shopping, it may not be necessary for an orthopedic surgeon to consult a PDMP prior to prescribing pain medicine to control post-surgical pain in a pediatric patient. Similarly, it makes sense for a physician who is contemplating initiating treatment with opioids, but believes the patient may be a risk for aberrant behavior or a physician who is treating patients with chronic pain with opioid analgesics, to consult the PDMP, if the PDMP data are reliable and accurate.

The key to determining which physicians should regularly check a PDMP prior to prescribing a controlled substance is to carefully consider the type of practice and the patient population of the physician. For example, the vast differences between providing care in an oncology practice, interventional radiology practice, or emergency department raise different issues whose "solutions for prescription drug abuse and diversion" cannot be understood or achieved through a one-size-fits-all mandate to check the PDMP.

5. One method that has been suggested to increase use of PDMPs is to leverage health information technologies such as electronic health records and clinical decision support tools that would streamline access to PDMP system. What are the benefits and risks of this type of integration? Do you think this is a mechanism that would be embraced by the provider community?

Currently, physicians and other health care providers are working to implement requirements related to electronic health records (EHR) and many are also incorporating decision support tools. While, ideally, vendors would offer options to integrate such information, the technical challenges remain significant for many aspects of EHR adoption and implementation. The first priority for PDMP adoption would be to ensure that such programs are modernized and have a public health focus. The AMA strongly supports efforts by the National Association of Boards of Pharmacy (NABP) to promote the "PMP InterConnect" program, an interstate data sharing hub that is operated by NABP at no cost to the states. NABP reports that by the first quarter of 2014, 25 states will be using the system and sharing data across state lines. Despite this success and positive impact on the public health, PDMPs are still being asked to comply with the Bureau of Justice Assistance (BJA) technological standards that reportedly are onerous and do not enhance the program. We understand that congressional leaders have urged BJA to approach this issue with greater flexibility, but it has not been forthcoming. NASPER grants do not include such requirements which should accelerate the uptake of the InterConnect program and enhance the quality of the data physicians and other prescribers and dispensers receive. Furthermore, the public health focus of NASPER is essential since over 95 percent of PDMP usage comes from healthcare providers.

6. A key component of our battle against prescription drug abuse is education—particularly as it relates to pain management and substance abuse. Would you describe the current system of education for physicians as it relates to these aspects of health care? What are the biggest problems with the current system of provider education and what can be done to improve it?

This response is specific for physicians and physicians-in-training pursuing an MD degree, and does not address the current state of education for doctors of osteopathy and dentists, or nurse practitioners and physicians assistants who may have independent prescribing privileges for controlled substances depending on their location.

Medical education curricula across the continuum address pain management and substance abuse. The organization that accredits undergraduate medical education, the Liaison Committee on Medical Education (LCME) contains a standard (ED-10) that includes pain management and substance abuse as subjects that should be present in required courses and clerkships in medical schools. In a survey of medical schools for the academic year 2012-2013, all 135 schools that responded included pain management and substance abuse within a course required for graduation. An opportunity exists to provide grants to fund innovative approaches and increased integration of pain topics into medical school curricula.

Pain management and substance abuse are also included in graduate medical education curricula. Several specialties address management of pain and/or substance abuse as important foci of the health care delivered by certified specialists, including Addiction Psychiatry and Medical Toxicology and Pain Medicine (a subspecialty of Anesthesiology, Neurology, Physical Medicine and Rehabilitation, and Psychiatry). In addition, the primary care specialties of Internal Medicine and Family Medicine require their trainees to demonstrate proficiency in the use of pharmacotherapy. More recently, attention has been devoted to developing targeted training to assist residents in managing issues at the interface of substance abuse and chronic pain.

In 2007 the National Institute on Drug Abuse (NIDA) partnered with eight medical schools around the country and the AMA's Innovative Strategies for Transforming Education of Physicians medical education research collaborative. These Centers of Excellence for Physician Information developed innovative drug abuse and addiction curriculum resources with the goal of helping to fill the gaps in current medical students/resident physician curricula. These curriculum resources are available on the NIDA Web site as a service to academic medical centers seeking scientifically—accurate instructional information on substance abuse.

At least 25 state medical societies sponsor courses on various aspects related to pain management and responsible opioid prescribing. Based on grant support from the Substance Abuse and Mental Health Services Administration and as part of the Prescriber Clinical Support System for Opioid Therapies (www.pcss-o.org), the AMA offers an updated comprehensive course on pain management that reflects contemporary concerns about the role of opioid analgesics in the management of chronic pain. Course materials are freely available. As part of our collaborative efforts in the PCSS-O, the AMA also is offering a series of free webinars on various aspects related to the intersection of pain, substance use disorders, and responsible opioid prescribing.

At least 10 states require that physicians complete continuing medical education (CME) in pain management and/or responsible controlled substance prescribing in order to renew their medical license. The AMA supports positive incentives to encourage prescribers to take CME in pain management and /or responsible controlled substance prescribing. National mandatory CME raises a number of concerns as a one-size—fits—all approach does not account for differential training that physicians receive including specialty, the state patterns of abuse and diversion, and the physician patient mix served. All of these are relevant factors in assessing whether CME in pain management and/or responsible controlled substance prescribing is appropriate for a physician. There are two areas where congressional funding to support research would support targeted, high-value evidence to drive policymaking. Funding research to evaluate the efficacy of existing state mandatory CME requirements, some of which have been in place for a number of years, would be highly beneficial. In addition, comparative effectiveness research to assess the impact on outcomes of modernized PDMPs that provide individualized patient-specific information at the point of care as compared to other broader strategies such as mandatory CME, would also improve the ability of lawmakers to craft solutions to meet the particular patterns of abuse and diversion in a particular state.

The opportunity remains to provide physician tools at the point of care that can be relied upon when making individualized, patient-centered determinations that we know will work if properly modernized. This is particularly true when addressing pain management or addiction. While PDMPs are not considered part of prescriber education, the information generated by a modernized PDMP can support both individualized clinical decision-making as well as targeted education efforts. The reauthorization of NASPER is an important opportunity to support informed physician clinical decision-making in order to ensure patients in need of patient management receive medically necessary care and those who require treatment for addiction are also correctly identified.

7. Many experts believe that prescribing guidelines related to opioids have the potential to reduce the instance of abuse. They are intended to help providers identify patients who are appropriate candidates for opioids and provide information on treating and monitoring them. It is my understanding many states have issued guidance but that research pointing to their effectiveness is

limited. Do you believe a defined set of prescribing guidelines has the potential to reduce abuse? What is the best way to go about formulating these guidelines and how do we maximize utilization of these guidelines?

Practice (or prescribing) guidelines are generally most applicable and effective when the disease or condition in question has readily identifiable, evidence-based diagnostic and treatment criteria. The question as stated does not acknowledge that the issues of appropriate pain management and reducing abuse/diversion of controlled substances cannot (or should not) be separated with respect to their overall impacts on public health. Pain in responsive human beings is a conscious experience involving interpretation of (painful) sensory input that is influenced by emotion, cognition, memory, interpersonal and social context and other factors. Because there is no objective indicator for pain (and pain cannot be proved or disproved) the best clinical approach in most circumstances is to assume that the patient is reporting a true experience, unless there is evidence to the contrary. Accepting a patient's complaint as valid does not require clinical identification of a physical cause, or demand the initiation of a specific treatment. In patients suffering from neuropathic or central pain syndromes, pain generating mechanisms develop and become persistent after the original injury has healed. Accordingly, the evaluation and assessment of persistent pain, in particular, has multiple dimensions.

Similarly, the ability of clinicians to identify individuals who are intent on diverting controlled substances, or who may eventually develop behaviors consistent with a substance use disorder is a (very) imprecise science. While we would agree that patients being considered for long term opioid therapy should be screened for a concurrent substance use disorder and for factors that may increase the risk of drugs with abuse liability, existing tools have limited utility. The occurrence of aberrant drug-related behaviors varies, exists along a continuum, and can be difficult to interpret. In general, the use of a universal precautions approach coupled with a comprehensive patient evaluation and risk assessment is recommended, along with a patient-centered treatment plan that incorporates a structured periodic review and compliance monitoring to inform the overall management strategy.

A balanced view in the development of policies, laws, and regulations should extend to the clinical setting. Pain is highly prevalent and destructive. Opioids and other controlled drugs are essential medications and have many legitimate medical uses. Prescription drug abuse, addiction, diversion and unintentional overdose are serious risks that must be considered whenever these drugs are potentially appropriate. An overt focus only on the abuse potential of a drug may lead to practice patterns that avoid their use even in the face of a generally accepted indication and situations where they are never used for a more controversial indication (e.g., chronic non-cancer pain) even when a subset of patients obtains clear benefit. Conversely, clinicians who are not sufficiently cognizant of the public health problem of prescription drug abuse may not apply appropriate risk assessment and management strategies. Pain is highly individualized, varies in its dimensions across practice settings, and presents unique challenges depending on the medical specialty. Accordingly, a "one-size—fits—all" approach to clinical guidance is insufficient and will not promote a balanced approach to addressing this problem. A common philosophical approach and tool kit that can be applied in an individualized manner is needed.

Question Posed The Honorable Kathy Castor

Dr. Stack, you mentioned in your testimony the benefits of PDMPs with up-to-date information for physicians to access. If Congress reauthorizes NASPER and fully funds it, what will this mean for combating prescription drug abuse?

> Reauthorization of NASPER and full appropriations is urgently needed to ensure that physicians across the country have patient-specific information at the point-of-care as part of their workflow to combat prescription drug abuse while ensuring patients with the legitimate need of pain management continue to have access to medically necessary care. In light of the telecommunication and technological advances we are experiencing—PDMPs will be able to offer individualized information to support clinical decision-making as well as population based data to establish a public health set of solutions and education programs for prescribers, state policy-makers, and the impacted communities. The AMA continues to strongly advocate for federal and state support to ensure PDMPs have the support they need. In the those instances when PDMPs have been adequately maintained and funded, are available at the point-of-care with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned. This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances. Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs.

Thank you again for the opportunity to provide the AMA's views on the importance of funding to support PDMPs. The AMA urges Congress to act swiftly to re-authorize NASPER and provide full appropriations.

Sincerely,

Steven J. Stack, MD
Chair, Board of Trustees

cc: James L. Madara, MD

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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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December 13, 2013

Mr. Robert MtJoy
CEO
Cornerstone Care, Inc.
7 Glassworks Road
Greensboro, PA 15338

Dear Mr. MtJoy:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 20, 2013, to testify at the hearing entitled "Examining Public Health Legislation to Help Local Communities."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your response to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, January 7, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Mr. Robert MtJoy
Chief Executive Officer

Attachment- Additional Questions for the Record

The Honorable Tim Murphy

1. **If the Family Healthcare Accessibility Act were enacted, what type of practitioners would you expect or hope would volunteer their time at a health center?**

   The Family Health Care Accessibility Act requires FTCA coverage extension is limited only to volunteers who are licensed health practitioners. Retired medical, dental, and behavior health care practitioners would make excellent volunteers and are often the individuals who approach health centers to donate their time and knowledge, but the expense of purchasing their own malpractice insurance is cost prohibitive for a retired practitioner.

   Even with the recent investments in programs like the National Health Service Corps, the demand for providers at health centers is outpacing the number of providers. Health centers have to compete with private providers when recruiting and retaining practitioners. These recruitment and retention challenges are compounded in rural areas. Over the last 20 years, the number of health care students in the United States choosing primary care careers in rural areas has declined precipitously due to a number of factors: lower compensation, professional isolation, less specialty support (especially for mental health services) and cultural isolation, poor-quality schools, housing, and lack of spousal job opportunities.

2. **Will you expound on what barriers Cornerstone Care faces when recruiting and retaining providers. How has this impacted access to care, specifically mental healthcare, in Southwestern Pennsylvania?**

   Cornerstone Care provides a comprehensive integrated primary and behavioral health care system that offers a team-based model of care to better meet the needs of our patients. Depending on the type of volunteers, mental health services could certainly be one area where Cornerstone Care could expand access to care if the Family Health Care Accessibility Act were passed into law as mental health providers are among our greatest recruitment and retention challenges. This difficultly is reflected in the longer time that open positions remain unfilled. For example, we have been unable to fill a psychiatrist vacancy since July 2012.